U.S. Department of Health and Human Services
National Institutes of Health
National Institute of Allergy and Infectious Diseases (NIAID)

RFP-NIH-NIAID-DMID-08-06
"Phase 1 Clinical Trial Unit for Therapeutics Against Infectious Diseases"

OMB Control Number 0990-0115

1. **OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.** http://www.fedbizopps.gov/

2. **SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1**
NOTE: The issuance of this solicitation does not commit the government to an award.

3. **Issue Date:**	4. **Due Date:** July 2, 2007	5. **Small Bus. Set-Aside:** [ ]Yes [X] No **8(a) Set-Aside:** [ ]Yes [X] No **NAICS:** 541710; 500 employees (See Part IV, Section L.)
March 1, 2007	**Time:** 3:00 P.M., EST	

6. **Just In Time:**	7. **Number of Awards:**	8. **Technical Proposal Page Limits:**
[X] No [ ] Yes (See Part IV, Section L.)	[X] Only 1 Award [ ] Multiple Awards	[ ] No [X] Yes (See Section J, Attachment 1, Packaging and Delivery of Proposal)

9. **Issued By:**

David T. Lisle
Contracting Officer, MIDRCB-B
Office of Acquisitions, DEA, NIH, NIAID
6700-B Rockledge Drive
Room 3214, MSC 7612
Bethesda, MD 20892-7612

10. [x] **NIAID reserves the right to make awards without discussion.**

11. **Options:**
[X] No
[ ] Yes (See Part IV, Section L.)

12. **Period of Performance:**
7 Years:
March 4, 2008 through March 3, 2015

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : David T. Lisle	**Name:** Barbara A. Shadrick	Director, OA
Phone: 301-451-2617	**Phone:** 301-496-7288	Address (see Block 9.)
Fax: 301-402-0972	**Fax:** 301-402-0972	
E-Mail: dlisle@niaid.nih.gov	**E-Mail:** bshadrick@niaid.nih.gov	

16. **COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.**

17. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Part III, SECTION J – Attachments)

18. **DELIVERY ADDRESS INFORMATION**

19. **Hand Delivery or Overnight Service:**	20. **U.S. Postal Service or an Express Delivery Service**
David T. Lisle, Contracting Officer Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	David T. Lisle, Contracting Officer Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with FAR 15.208 entitled "Submission, Modification, Revision, and Withdrawal of Proposals." FACSIMILE AND E-MAIL SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

13. DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR *(i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval)* WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This contract is to fulfill a requirement of the Division of Microbiology and Infectious Diseases (DMID), NIAID, NIH, DHHS through the provision and management of a Phase 1 Clinical Trial Unit for Therapeutics Against Infectious Diseases.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is $_____.

b. The fixed fee for this contract is $_____. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is $_____.

d. Total funds currently available for payment and allotted to this contract are $_____, of which $_____ represents the estimated costs, and of which $_____ represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

e. It is estimated that the amount currently allotted will cover performance of the contract through _____.

f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award. (See Attachment 8 for Advance Understandings specific for this RFP.)

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated January 5, 2007, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

In addition to the required reports set forth elsewhere in the Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. Please refer to the "Reporting Requirements and Deliverables" in SECTION J - List of Attachments.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11 including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institute of Allergy and Infectious Diseases, NIH, DHHS
Office of Acquisitions, DEA
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at, DMID, NIAID, NIH, DHHS.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-8, Inspection of Research and Development - Cost-Reimbursement** (May 2001).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the STATEMENT OF WORK in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the items specified in the delivery schedule described in SECTION C of this contract.

The items specified in the delivery schedule described in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified in the delivery schedule described in SECTION C and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract.

ARTICLE F.2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at: http://www.acquisition.gov/comp/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

The personnel specified in this ARTICLE are considered to be essential to the work to be performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this article. The contract may be amended from time to time during the course of the contract to either add or delete personnel, as appropriate.

NAME	TITLE
[To be specified prior to award]	

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

(1) Invoices/financing requests shall be submitted as follows:

(a) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN266200800006C.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, i.e. N01-AI-80006.)

(b) An original and two copies to the following designated billing office:

Contracting Officer
National Institute of Allergy and Infectious Diseases, NIH, DHHS
Office of Acquisitions, DEA
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

(2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 496-0612.

b. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with P.L. __ - __ and the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of the above referenced contract."

c. The following is a listing of expenditure categories that may be required to be reported on your invoice:

Expenditure Category

(1) Direct Labor
(2) Other Professional Personnel
(3) Personnel - Other
(4) Fringe Benefits
(5) Accountable Personal Property
(6) Materials/Supplies
(7) Travel
(8) Consultant Costs
(9) Premium Pay
(10) Subcontract Costs
(11) Other Direct Costs
(12) Indirect Costs
(13) G&A Expense
(14) Total Cost
(15) Fee
(16) Total Cost Plus Fixed Fee

ARTICLE G.4. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC 7540
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.5. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication entitled, **Contractor's Guide for Control of Government Property**, which can be found at:

http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted at least once during the performance of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase 1 has been approved by the Project Officer, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

The information below is a summary of the NIH Policy Announcement:

The contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.3. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan. The Data and Safety Monitoring Plan shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.4. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

ARTICLE H.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.6. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.7. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-2000. This document may be accessed on the Internet at http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm.

ARTICLE H.8. OMB CLEARANCE or CLINICAL EXEMPTION

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed. In addition, in accordance with 5 CFR 1320.3(h)(5), this requirement may be eligible for a Clinical Exemption to OMB Clearance requirements subject to the approval of the NIH Clinical Exemption Review Committee (CERC). The clinical exemption must be obtained and written approval to proceed received from the Project Officer and Contracting Officer before data is collected under this contract or any subcontract.

ARTICLE H.9. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract.

(2) The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

(1) Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

(2) Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the Contract Specialist shall be included as a contact for notification purposes.

ARTICLE H.10. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b.

Public Law and Section No.*	**Fiscal Year***	**Dollar Amount of Salary Limitation***

c. Payment of direct salaries is limited to the Executive Level rate which was in effect on the date(s) the expense was incurred.

[*Applicable information to be included at award]

ARTICLE H.11. INFORMATION SECURITY

The Statement of Work (SOW) requires the contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf

a. Information Type

[X] Administrative, Management and Support Information:
[ ] Mission Based Information:

b. Security Categories and Levels

Confidentiality	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Integrity	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Availability	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Overall	**Level:**	**[X] Low**	**[ ] Moderate**	**[ ] High**

c. Position Sensitivity Designations

(1) The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

[ ] **Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI)**. Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

[ ] **Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI)**. Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[X] **Level 1: Non Sensitive (Requires Suitability Determination with an NACI)**. Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

(2) The contractor shall submit a roster, by name, position and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: http://ais.nci.nih.gov/forms/Suitability-roster.xls.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: http://ais.nci.nih.gov.

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(3) Contractor/subcontractor employees shall comply with the HHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor/subcontractor employees may begin work under the contract after the contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c. (2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the contractor/subcontractor employee to work under the contract.

d. Information Security Training

The contractor shall ensure that each contractor/subcontractor employee has completed the NIH Computer Security Awareness Training course at: http://irtsectraining.nih.gov/ prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract.

The contractor shall maintain a listing by name and title of each contractor/subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by contractor/subcontractor staff shall be included on this listing. The listing of completed training shall be included in the first technical progress report. (See Article C.2. Reporting Requirements.) Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.

Contractor/subcontractor staff shall complete the following additional training prior to performing any work under this contract:

e. Rules of Behavior

The contractor/subcontractor employees shall comply with the NIH Information Technology General Rules of Behavior at: http://irm.cit.nih.gov/security/nihitrob.html.

f. Personnel Security Responsibilities

The contractor shall perform and document the actions identified in the "Employee Separation Checklist", attached and made a part of this contract, when a contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

(1) Contractor Agreement

The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

-18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
-18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
-Public Law 96-511 (Paperwork Reduction Act)

(2) Contractor-Employee Non-Disclosure Agreements

Each contractor/subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

ARTICLE H.12. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN266200800XXC.

ARTICLE H.13. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.14. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS** (**1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.15. ANTI -LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.16. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at : http://ott.od.nih.gov/NewPages/64FR72090.pdf. is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools," "research materials," and "research resources" are used interchangeably and have the same meaning.

ARTICLE H.17. SHARING RESEARCH DATA

The data sharing plan submitted by the contractor is acceptable. The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H.18. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

The Policy requests that beginning May 2, 2005, NIH-funded investigators submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html.

ARTICLE H.19. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING **ARTICLE I.1 GENERAL CLAUSE LISTING(S)** WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

General Clauses for a Cost-Reimbursement Research and Development Contract

The complete listing of these clauses may be accessed at:
http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clauses.jsp

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

FAR Clauses **52.215-15, Pension Adjustments And Asset Reversions** (October 2004); **52.215-18, Reversion Or Adjustment Of Plans For Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, **52.215-19, Notification Of Ownership Changes** (October 1997), are deleted in their entirety.

Alternate IV (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications** (October 1997) is added.

Alternate II (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (September 2006) is added.

FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. ***[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]***

Alternate I (February 2002), of FAR Clause **52.232-25, Prompt Payment** (February 2002) is deleted.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

(1) FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

(2) FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

(3) FAR Clause **52.224-2, Privacy Act** (April 1984).

(4) FAR Clause **52.227-14, Rights in Data - General** (June 1987).

(5) **Alternate II** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

(6) **Alternate III** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

(7) **Alternate V** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

(8) FAR Clause **52.227-15, Representation of Limited Rights Data and Restricted Computer Software** (June 1987).

(9) FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

(10) FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).

(11) FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (April 1998).

(12) FAR Clause **52.230-6, Administration of Cost Accounting Standards** (April 2005).

(13) FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

(14) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

(15) FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June2003).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

(1) HHSAR Clause **352.223-70, Safety and Health** (January 2001).

(2) HHSAR Clause **352.224-70, Confidentiality of Information** (March 2005).

(3) HHSAR Clause **352.270-8, Protection of Human Subjects** (March 2005).

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

(1) **NIH (RC)-7, Procurement of Certain Equipment** (April 1984) (OMB Bulletin 81-16).

(2) **NIH(RC)-11, Research Patient Care Costs** (4/1/84).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

a. FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees** (December 2004)

(a) Definition. As used in this clause--

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to--

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and
(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are provided as either attachments to this RFP or can be accessed through the provided web links:

ATTACHMENTS TO THIS SOLICITATION: (The following documents are incorporated into this RFP.)

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 4:	Reporting Requirements and Deliverables	See Attachment Section at the end of this RFP
Attachment 5:	Additional Technical Proposal Instructions	See Attachment Section at the end of this RFP
Attachment 6:	Additional Business Proposal Instructions and Uniform Budget Assumptions	See Attachment Section at the end of this RFP
Attachment 7:	DMID-Funded Clinical Research Support Services Contracts	See Attachment Section at the end of this RFP
Attachment 8:	Advance Understandings	See Attachment Section at the end of this RFP

DOCUMENTS TO BE ATTACHED TO THE TECHNICAL PROPOSAL: (The following documents must be completed, where applicable, and submitted with the Technical Proposal. They can be located at the electronic Web links provided below and are, therefore, not included in the Attachment Section at the end of this RFP.)

Title	Location
Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement	http://rcb.cancer.gov/rcb-internet/forms/IT-security-nondisclosure.pdf
Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf
Targeted/Planned Enrollment Table	http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf
Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (formerly Optional Form 310	http://rcb.cancer.gov/rcb-internet/forms/of310.pdf

DOCUMENTS TO BE ATTACHED TO THE BUSINESS PROPOSAL: (The following documents must be completed, where applicable, and submitted with the Business Proposal. They can be located at the electronic Web links provided below and are, therefore, not included in the Attachment Section at the end of this RFP.)

Title	Location
Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/SBA Plan Nov 2005.pdf

INFORMATIONAL DOCUMENTS: (The following documents and reports will become part of any contract resulting from this RFP and will be required during contract performance. They can be located at the electronic Web links provided below and are, therefore, not included in the Attachment Section at the end of this RFP.)

Title	Location
Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Privacy Act System of Records *System of Records No. 09-25-0200 is applicable to this RFP.*	http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm
Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Government Property Schedule	http://www.niaid.nih.gov/contract/forms/form9.pdf
Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf
Research Patient Care Costs, NIH(RC)-11	http://www.niaid.nih.gov/contract/forms/nih-rc-11.pdf
Inclusion Enrollment Report	http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

SECTION K can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the Online Representations and Certifications Application (ORCA) at: https://orca.bpn.gov/ and complete the Representations and Certifications; and

2. Complete, and include as part of your BUSINESS PROPOSAL, SECTION K which can be accessed electronically from the INTERNET at the following address:
   http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2004)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", *"writing"*, or *"written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show–

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and–

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want

used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted,

the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iv) A summary of the rationale for award.
(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

b. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.

(2) The small business size standard is 500 employess.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. **TYPE OF CONTRACT AND NUMBER OF AWARDS**

It is anticipated that one award will be made from this solicitation and that the award will be made on/about March 4, 2008.

It is anticipated that the award from this solicitation will be a multiple-year, cost reimbursement, completion type contract with a period of performance of seven years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

d. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the annual effort to be approximately 17.5 total FTEs. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

e. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

g. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

h. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors are specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

i. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

j. **SERVICE OF PROTEST** (SEPTEMBER 2006) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
National Institute of Allergy and Infectious Diseases, NIH, DHHS
Office of Acquisitions, DEA
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

k. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70 (January 2006)

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it appears to offer the best value to the Government and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement, completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J, hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments. See also, Additional Technical Proposal Instructions, Attachment 5.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments. See also, Additional Business Proposal Instructions and Uniform Budget Assumptions, Attachment 6.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD.)

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY). However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or

amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Part IV, Section M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Standards for Privacy of Individually Identifiable Health Information**

The Department of Health and Human Services (DHHS) issued final modifications to the “Standards for Privacy of Individually Identifiable Health Information,” the “Privacy Rule,” on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as “covered entities” must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on “Am I a covered entity?” Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

(10) **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(11) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

(12) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(13) **Past Performance Information**

a) Offerors shall submit the following information as part of their business proposal.

A list of the last five contracts completed during the past three years and the last three contracts awarded, currently being perfomed, that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any subcontract over $650,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b) The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(14) **Prohibition on Contractor Involvement with Terrorist Activities**

The contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

(15) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).

b) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

d) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

NOTE: Offerors are also advised to also refer to the information included in Attachment 5, "Additional Technical Proposal Instructions" when preparing their Technical Proposal.

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Project Objectives, NIH-1688-1**

The offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an **Institution of Higher Education:** The form MUST be completed in its entirety.
- For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, **"INSTRUCTIONS:"**

b) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated

as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

c) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in SECTION M - Evaluation Factors for Award of this solicitation.

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

IMPORTANT NOTE TO OFFERORS: The following paragraphs(5) through (14) shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

(5) **Human Subjects**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (MARCH 2005)

(a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The OpDiv will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OHRP, (telephone: 301-496-7005), is recommended.

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. The contracting officer will direct the offeror/contractor to the OHRP IRB Registration and Assurance Filing website, found at http://www.hhs.gov/ohrp/ or to the physical address if the offeror/contractor cannot access the Internet. HHS regulations for the protection of human subjects may be found at:

http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html

(f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

(6) **Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.

- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.

- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(7) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. You may download the information at this site at no cost and modify it, if desired. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at
http://www.centerwatch.com/order/pubs_profs_protect.html.
In addition, the NCI sponsors an online training course at:
http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp.
If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

(8) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), ***and applies to research subjects of all ages***.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research," at: (http://www.nih.gov/news/crp/97report/execsum.htm).

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

NOTE 1: *For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at: http://www.whitehouse.gov/OMB/fedreg/ombdir15.html.*

NOTE 2: *If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.*

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase 3 clinical trials*** require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions -

Significant Difference. *The definition of an **"NIH-Defined Phase 3 clinical trial"** can also be found at this website.) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form entitled, "Targeted/Planned Enrollment Table," when <u>preparing your response</u> to the solicitation requirements for inclusion of women and minorities. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP)

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the form entitled, "Inclusion Enrollment Report," for <u>reporting in the resultant contract</u>.

(9) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are *clear and compelling* reasons not to include them. (See examples of Justifications for Exclusion of Children below). For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The “Human Subjects” section of your technical proposal should provide either a description of the plans to include

children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.

    - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.

    - The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.

        - A separate, age-specific study in children is warranted and preferable.
        - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
        - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
        - Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
        - Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
        - Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
        - Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a “child,” and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of “child” for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

(10) **Research Involving Prisoners as Subjects**

a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS-funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/prisoner.htm

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:

   a) to describe the prevalence or incidence of a disease by identifying all cases, or
   b) to study potential risk factor associations for a disease, and

2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2-7) and determined and documented that:

   a) the research presents no more than minimal risk, and
   b) no more than inconvenience to the prisoner-subjects, and
   c) prisoners are not a particular focus of the research.

For more information about this Waiver see http://www.hhs.gov/ohrp/special/prisoners/Prisoner waiver 6-20-03.pdf

(11) **Research Involving Human Fetal Tissue**

Human Fetal Tissue means tissue or cells obtained from a dead human fetus, including human embryonic stem cells, human pluripotent stem cells and human embryonic germ cells.

The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

By signing the face page of the proposal, the offeror (authorized institutional official) certifies that researchers using human fetal tissue are in compliance with 42 USC 289g-2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to profit, and does not include reasonable payment for costs associated with the collection processing, preservation, storage, quality control or transportation of these tissues.

Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local law.

(12) **Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)**

Recombinant DNA Molecules are either 1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or 2) DNA molecules that result from the replication of those described in 1).

The NIH Guidelines for Research Involving Recombinant DNA Molecules (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules, at:
(http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html)
and any subsequent revisions to the Guide Notice) stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the NIH Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and//or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the project officer and contracting officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of NIH funding for any work related to Recombinant DNA Research or a requirement for the contracting officer's prior approval of any or all Recombinant DNA projects under any contract awarded from this solicitation. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm).

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the project officer and contracting officer.
(http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)

(13) **Human Embryonic Germ Cell (HEGC) Research**

1. Guidelines.

Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://stemcells.nih.gov/policy/guidelines.asp) (only the information regarding human embryonic germ cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human embryos. See NIH Guide for Grants and Contracts Notice NOT-OD-02-049, requiring that offerors/contractors submit certain documents to the Human Pluripotent Stem Cell Review Group (HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.

All offerors should read the "NIH Guidelines" (http://stemcells.nih.gov/policy/guidelines.asp) if they either: (1) propose to respond to the Statement of Work requirements by conducting research that uses human embryonic germ cells or, (2) are responding to a Statement of Work that requires the use of human embryonic germ cells.

Offerors may obtain copies of these Guidelines from the website above or from the contact person listed in this solicitation.

2. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If the offeror intends to fulfill the requirements of the Statement of Work by performing research using human embryonic germ cells, it must so state in its proposal.

If the offeror's proposal includes research using human embryonic germ cells and it receives a contract award, the contractor may not perform any research using these human embryonic germ cells until the Human Pluripotent Stem Cell Review Group (HPSCRG) has reviewed and approved the documentation furnished as prescribed in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" at: (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) and the contracting officer has notified the contractor of the approval in writing.

The resultant contract will be divided into discrete phases or option period(s). During Option Period(s)/Phase(s) N/A of the contract, the contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at: (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html), to the contracting officer. This documentation will be forwarded for review and approval to the HPSCRG.

If the HPSCRG disapproves the documentation presented by the contractor, the Contracting Officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the contracting officer will notify the contractor in writing that research using the human embryonic germ cells may commence.

Research involving the use of human embryonic germ cells shall not be conducted under the contract until the HPSCRG review and approval have been obtained, and the contracting officer has provided written notice of such approval to the contractor.

(14) **Human Embryonic Stem Cell (HESC) Research**

On August 9, 2001, the President announced the criteria that must be met for Federal funds to be used for research on existing human embryonic stem cell lines. These criteria were subsequently published by the NIH at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. The following eligibility criteria must be met:

1. The derivation process (which commences with the removal of the inner cell mass from the blastocyst) must have already been initiated prior to August 9, 2001;
2. Prior to August 9, 2001, the embryo from which the stem cell line was derived no longer had the possibility of development as a human being;
3. The stem cells must have been derived from an embryo that was created for reproductive purposes;
4. The embryo was no longer needed for these purposes;
5. Informed consent must have been obtained for the donation of the embryo;
6. No financial inducements were provided for the donation of the embryo.

To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem Cell Registry ("the NIH Registry") that lists the human embryonic stem cells that meet the eligibility criteria. This registry is available at: http://stemcells.nih.gov/registry/.

Research involving the derivation of new stem cells from human embryos or the use of human embryonic stem cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal funding.

If a particular human embryonic stem cell line has not been required by the Statement of Work, an offeror proposing research involving human embryonic stem cells must cite a human embryonic stem cell line that is listed in the NIH Registry in its proposal.

(15) **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase 3 clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase 1 and Phase 2 clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multisite trials)
- Institutional Review Board (IRB - required)

For multi-site Phase 1 and Phase 2 trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase 1 and Phase 2 trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

(16) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(a) **Sharing Research Data**

*[Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.]*

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.

(17) **Information Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, "INFORMATION SECURITY."

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source. The National Institute of Standards and Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal information system and its information.

The Statement of Work (SOW) requires the successful offeror to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies the following requirements apply to this solicitation:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf

(a) Information Type

[X] Administrative, Management and Support Information:
[ ] Mission Based Information:

(b) Security Categories and Levels

Confidentiality	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Integrity	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Availability	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Overall	**Level:**	**[X] Low**	**[ ] Moderate**	**[ ] High**

(c) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each contractor (including subcontractor) employee that the successful offeror proposes for work under the contract. For proposal preparation purposes, the following designations apply:

[ ] Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI). Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

[ ] Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[X] Level 1: Non Sensitive (Requires Suitability Determination with an NACI). Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

Upon award, the contractor will be required to submit a roster of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a federal information system(s). The Government will determine and notify the Contractor of the appropriate level of suitability investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: http://ais.nci.nih.gov/forms/Suitability-roster.xls

Upon receipt of the Government's notification of applicable Suitability Investigations required, the contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: http://ais.nci.nih.gov.

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(d) Information Security Training

HHS policy requires contractors/subcontractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor/subcontractor employee has completed Computer Security Awareness Training prior to performing any contract work, and thereafter completing annual refresher course during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

Additional security training requirements commensurate with the position may be required as defined in NIST Special Publication 800-16, Information Technology Security Training Requirements (http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf). This document provides information about information security training that may be useful to potential offerors.

(e) Offeror's Official Responsible for Information Security

The offeror shall include in the "Information Security" part of its Technical Proposal the name and title of its official who will be responsible for all information security requirements should the offeror be selected for an award.

(f) References

(1) Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf
(2) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(3) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/

The following NIST publications may be found at the following site: http://csrc.nist.gov/publications/
[Note: The search tool on the left side of this page provides easy access to the documents.]

(4) NIST Special Publication 800-16, Information Technology Security Training Requirements; and Appendix A-D
(5) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
(6) NIST SP 800-26, Revision 1, Computer Security
(7) NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems
(8) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and
Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D
(9) NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
(10) FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
(11) FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

c. BUSINESS PROPOSAL INSTRUCTIONS

NOTE: Offerors are also advised to also refer to the information included in Attachment 6, "Additional Business Proposal Instructions and Uniform Budget Assumptions" when preparing their Business Proposal.

(1) **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) **Proposal Cover Sheet**

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) **Information Other than Cost or Pricing Data**

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified.

Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $650,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

(4) **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(5) **Salary Rate Limitation in Fiscal Year 2007**

Offerors are advised that pursuant to P.L. **, no NIH Fiscal Year 2007 (October 1, 2006 - September 30, 2007) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. ** applies only to Fiscal Year 2007 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. ** states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of Executive Level I*."

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/06tables/indexSES.asp

***Note to Offerors:** The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year 2007 Executive Level I Salary rates.*

***Pending Passage of Legislation.*

(6) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $550,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $550,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

23% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(7) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(8) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $550,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). TheNAICS codes can be found at:
http://www.sba.gov/size

The Department of Commerce website for the annual determination for NAICS codes* is:
http://www.arnet.gov/References/sdbadjustments.htm.

**Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

*Note: FAR Subpart 9.6 defines “Contractor team arrangements” to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(9) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate

experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(10) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

c) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38**, (May 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

d) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2006)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds, as specified in FAR 52.232-22. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modification.

However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments nor is the Contractor obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232-22, shall supersede the Limitation of Cost clause found in the Section I, Contract Clauses.

(End of provision)

f) **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(11) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(12) **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(13) **Representations and Certifications - SECTION K**

One copy of SECTION K (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor. SECTION K can be found at: http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

(14) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

(15) **Certification of Visas for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD

a. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government intends to make an award to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

b. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

(a) Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation in the proposed research plan, or provide sufficient information on the research subjects to allow a determination by NIAID that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

(b) Women and Minorities

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase 3 clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:

    - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
    - overriding factors dictate selection of subjects); or
    - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:

    - inclusion of those groups would be inappropriate with respect to their health; or
    - inclusion of those groups would be inappropriate with respect to the purpose of the research.

- For NIH-defined Phase 3 clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities

inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

(c) **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

If the information provided in your proposal about the inclusion of children is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

(d) **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase 3 clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase 1 and 2 clinical trials, the establishment of a DSMB is optional. The reviewers will rely on the Statement of Work and Section L in the solicitation, as well as any further technical evaluation criteria in this Section M, as applicable, for the solicitation's specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will consider the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this

section of the proposal may be rated “unacceptable” (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or “acceptable.” If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for data and safety monitoring is still found to be unacceptable, then your proposal may not be considered further for award.

c. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy. If your proposal does not include a plan or if the plan in your proposal is considered “unacceptable,” and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered “unacceptable” by the Government after discussions, your proposal may not be considered further for award.

d. **TECHNICAL EVALUATION CRITERIA**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes. Sub-criteria, if not weighted, should be considered to be of equal importance.

CRITERIA	**WEIGHT**
A. TECHNICAL PLAN/APPROACH	**25**

The Offeror's overall understanding of the objectives and requirements of the RFP, ability to identify problems and recommend and implement solutions, and ability to enhance the achievement of the scientific goals of the overall program will be evaluated for the following elements.

1. Clinical Trials: Ability to design, conduct and analyze the results of Phase 1 safety, pharmacokinetic and pharmacodynamic clinical trials, as evidenced by the soundness, appropriateness, adequacy and feasibility of the scientific, technical and operational plans for the case study: *Phase 1 Clinical Trial of Novel Antibiotic*.

2. Trial-related Materials: The completeness, soundness and adherence to GCP principles of the following:

    a. plans and procedures for generating electronic and paper Case Report Forms (CRFs), including examples of CRFs produced for Phase 1 pK/pD clinical trials;

    b. table of contents of a Manual of Operations (MOO) and the data management section of a MOO;

    c. examples of previously generated materials/documents; and

    d. plan and procedures for reviewing, updating and distributing trial-related materials.

3. Trial Population and Enrollment Requirements:

   For the offeror and all proposed affiliated clinical sites:

   a. Documented access to the number of healthy subjects required to serve as subjects, and ability to recruit and retain subjects from the general population, including members of minority populations and both genders;

   b. Ability to identify anticipated recruitment and retention problems and difficulties that may arise; and adequacy of proposed approaches to overcome or minimize anticipated problems and difficulties.

4. Affiliated Clinical Sites:

   a. Adequacy, feasibility and appropriateness of plans for accessing and utilizing affiliated clinical sites to meet contract requirements, including ensuring access to adequate numbers of healthy volunteers and ability to fully enroll, conduct and complete clinical trials within specified time frames.

   b. Appropriateness and adequacy of the proposed decision tree for determining when affiliated clinical sites will be required and the criteria to be used to select sites for specific trials.

5. Standard Operating Procedures

   Adequacy, feasibility and appropriateness of proposed standard operating procedures for determining minimal staffing requirements and credentialing of staff for inpatient units, managing emergencies in inpatient units, developing, reviewing, and approving new protocols, handling, shipping, storaging and dispensing of investigational products, and providing quality management.

B. PERSONNEL **25**

1. Principal Investigator: Appropriateness and adequacy of the training, expertise, experience, and level of effort of the proposed Principal Investigator with respect to the following:

   a. Design, conduct and analysis of Phase 1 clinical trial to evaluate the safety, pharmacokinetics and pharmacodynamics of therapeutic candidates, particularly for the treatment of infectious diseases.

   b. The management and oversight of clinical trials, with respect to ensuring adherence to Good Clinical Practices, food and drug law (21 CFR312), and other regulatory requirements governing the conduct of research involving human subjects, and protocol-specific requirements for the conduct of research involving human subjects, including the development and implementation of standard operating procedures and plans for quality assurance/quality control, the identification of performance problems and deficiencies, and the implementation of remedial actions to address performance problems and deficiencies.

   c. Collaborations with industry and clinical research support services contractors with respect to study design, statistical analysis, preparation of and reporting study data for Investigational New Drug (IND) applications, data management and quality control, and clinical site monitoring.

   d. Documented active physician's licensure in the United States.

2. Pharmacologist and Pharmaco-Toxicologist: Appropriateness and adequacy of the training, expertise, experience, and level of effort of the proposed Pharmacologist/Pharmaco-Toxicoligist with respect to the following:

    a. Interpreting pre-clinical information, the design of clinical trials of Phase 1 drug candidates.

    b. Collaboration with industry.

3. Other Scientific and Technical Personnel: Appropriateness and adequacy of the training, expertise, experience, and level of effort of other proposed scientific and technical personnel of the offeror and all proposed subcontractors, including the adequacy of the proposed mix of staff, training, expertise, and experience to carry out contract requirements with respect to the following:

    a. Conduct of clinical trials of candidate therapeutics for infectious diseases according to Good Clinical Practices, food and drug law (21 CFR312), and other regulatory requirements governing the safe conduct of research involving human subjects, and protocol-specific requirements for the conduct of research involving human subjects.

    b. Receipt, packaging, distribution and tracking of investigational products.

    c. Collection and processing of clinical specimens and the conduct of protocol-relevant tests to determine patient eligibility and safety evaluations.

    d. Development, maintenance and support of the data management system in general and as it pertains to each specific protocol.

    e. Packaging, labeling and transport of clinical specimens.

    f. Data entry, management and quality control.

C. PROTOCOL IMPLEMENTATION AND OVERSIGHT **20**

Ability to implement and oversee the conduct of clinical trials as evidenced by the appropriateness and adequacy of proposed plans for developing, implementing, and/or maintaining the following:

1. Safety Oversight:

    a. Internal plans and procedures for assuring appropriate safety oversight for subjects and compliance with all safety guidelines and regulations at the Offeror's institution and at all proposed affiliated clinical sites, including designation and use of Independent Safety Monitors and Back-up Monitors.

    b. Plans for clinical site monitoring via an independent Clinical Site Monitoring Team; developing corrective actions to address performance problems identified through the clinical site monitoring process; and ensuring effective communication with NIAID on site performance.

    c. System of records for all documentation required for the conduct of clinical trials and system for reporting safety data and information from clinical trials.

2. Data Management and Quality Control:

   a. Proposed plans and procedures to establish, operate, maintain and update computer-based systems and to implement related system procedures for the collection, management and quality control of all clinical and laboratory research data and for the management and reporting of data and other information, including data entry system, procedures for computer-based randomization, data integrity, data edits, triggering of halting rules, data transfer, storage, freezing and locking, system security, and compliance with regulatory requirements.

   b. Standards and procedures for the quality control of trial data collected from the Offeror and all proposed affiliated clinical sites.

   c. Proposed plans and procedures for the provision of the database to regulatory agencies and industry collaborators.

3. Trial Investigational Product Management and Accountability:

   Procedures for receiving, packaging, labeling, storing, dispensing and tracking of investigational products and for monitoring storage conditions.

4. Storage, Shipping and Tracking of Clinical Specimens:

   a. Procedures for classification, labeling, documentation, shipping and tracking of clinical specimens, including plan to meet requirements of the International Transport Association for shipping of dangerous goods.

   b. Sample Standard Operating Procedure for inventory control system for clinical specimens.

5. Quality Assurance/Quality Control (QA/QC):

   a. Plan to standardize contract research processes to ensure that the conduct of any clinical trial and all data generated meet all regulatory standards and other standards, including Standard Operating Procedures for establishing and maintaining the QA/QC process, the process for internal quality audits, and remediation procedures for addressing issues.

   b. Plans to accommodate independent auditors.

D. FACILITIES AND OTHER RESOURCES **20**

The availability, adequacy and suitability of the clinical research facilities, equipment and other resources of the Offeror and all proposed subcontractors for the conduct of clinical trials, including the capacity to perform special testing as needed, in accordance with Federal regulatory requirements and guidelines, including Good Clinical Practice, NIH, NIAID and DMID policies and procedures, and the scope and requirements of the RFP. This includes facilities for:

1. Outpatient and inpatient clinical trials;
2. Clinical and clinical research laboratories;
3. Research pharmacy; and
4. General clinical research

E. PROJECT MANAGEMENT **10**

1. Overall Project Management: Adequacy and suitability of:

   a. Plans for the staffing, organization, distribution of responsibilities, leadership and lines of authority for carrying out contract requirements.

   b. Systems proposed for tracking contract activities and monitoring progress, timelines and budgets.

   c. Plans for communication between the Principal Investigator and the Project Officer and the Contracting Officer, as well as established lines of communication among all performance sites and activities.

   d. Plan for the Contractor to safeguard data and materials provided by third parties or the Government, as well as data generated under the contract.

2. Subcontract Acquisition and Management: Adequacy and suitability of subcontract acquisition and management with respect to:

   a. Plan for soliciting, evaluating, awarding and managing subcontracts.

   b. Proposed methods to assess subcontractor performance, identify performance problems and approaches for their remediation, including non-compliance with subcontract terms and conditions, and implement corrective actions when necessary.

   c. Expertise and experience of proposed staff responsible for the technical, financial and business management of subcontracts.

TOTAL POSSIBLE POINTS **100**

e. **PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

f. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Complexity and variety of the work SDB concerns are to perform
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

g. **PRE-AWARD SITE VISITS OR SITE AUDIT**

Offerors determined, upon completion of the Scientific/Technical Peer Review, to be in the Competitive Range may be subject to auditing of their clinical research facilities and QA/QC capabilities. The decision to audit specific facilities will be made by the Project Officer. If audits are performed during the negotiations, the results of the audits will be a factor in final selection for award of a contract. Offerors, including proposed subcontractors, will be requested to make all non-proprietary records, including previous regulatory inspection reports, and staff available in response to a pre-award site visit or audit by the NIAID or its designee. ***Due to timeline requirements, pre-award site visits may be made with short notice. Offerors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.***

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachments applicable to this RFP as specified in SECTION J - List of Attachments

PACKAGING AND DELIVERY OF THE PROPOSAL

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals.

SUBMISSION OF PROPOSALS BY FACSIMILE OR E-MAIL IS **NOT** ACCEPTABLE.

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"**RFP NO. NIH-NIAID-DMID-08-06**
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. PAPER COPIES and CD-Rom to:

If Hand Delivery or Express Service	If using U.S. Postal Service
David T. Lisle Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	David T. Lisle Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

C. NUMBER OF COPIES:

TOTAL PAGE COUNT DOES NOT INCLUDE: Title and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section.

PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES.

FORMATTING AND LAYOUT:
Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals.

Documents submitted using Adobe .pdf shall be submitted using a .pdf searchable format.

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).
- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

CREATING AND NAMING ELECTRONIC FILES:

1. A separate CD should be submitted for the Technical Proposal and Business Proposal information. *Offerors who submit both Technical and Business Proposals on the same CD will be required to resubmit them on separate CDs.*

2. It is requested that the Technical Proposal be submitted as one document.

   Note: if multiple files are submitted for the either proposal, please include the name of the section in the file name.

   EXAMPLE: XYX Company-08-06-Technical-Approach-07-02-07

3. CDs should be named using the following format:

   Technical Proposal: ***Company name-RFP number-technical-date***
   Business Proposal: ***Company name-RFP number-business-date***

THE NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS REQUIRED OF EACH PART OF YOUR PROPOSAL ARE AS SPECIFIED BELOW.

PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

OFFERORS MUST CERTIFY THAT THE INFORMATION IN THE PAPER AND ELECTRONIC COPIES IS EXACTLY THE SAME.

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Six (6) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	**Not to Exceed 200 pages (inclusive of all Attachments and Appendices)**
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Business Proposal	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.**	N/A

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-08-06
RFP Title: Phase 1 Clinical Trial Unit for Therapeutics Against Infectious Diseases

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **May 14, 2007**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
OA, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

Attn: David T. Lisle
RFP-NIH-NIAID-DMID-08-06
FAX# (301) 402-0972
Email: dlisle@niaid.nih.gov

STATEMENT OF WORK

Phase 1 Clinical Trial Unit for Therapeutics Against Infectious Diseases
RFP NIH-NIAID-DMID-08-06

BACKGROUND and INTRODUCTION

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), strives to understand, treat and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents other than HIV. This includes basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics that is funded through a variety of research grants and contracts.

The evaluation of new and improved vaccine and therapeutic candidates in clinical trials and clinical studies is an essential element of the efforts of DMID. Through an extensive network of grant and contract research programs, DMID supports a broad range of clinical research, including single-site and multi-center Phase 1, Phase 2, Phase 3, and Phase 4 clinical trials of bacterial, viral and parasitic vaccines, therapeutics, and other biologics and drugs as preventive and therapeutic measures against infectious diseases in people of all ages and risk categories. Clinical trials and clinical studies are also supported to evaluate the safety and efficacy of vaccines and therapeutics against potential agents of bioterrorism, including NIAID priority biodefense pathogens (http://www3.niaid.nih.gov/Biodefense/bandc_priority.htm), and to address other critical public health needs, such as those related to emerging and re-emerging infectious diseases, such as Severe Acute Respiratory Syndrome (SARS) and avian influenza. Support is also provided for a variety of other studies, including: targeted surveillance for pathogens of interest in trial populations; reevaluation of current vaccine formulations, schedules and modes of delivery; and evaluations of novel investigational product delivery systems.

The Division also supports substantial preclinical research efforts to develop new therapeutics. It is anticipated that these efforts will produce many promising investigational products that will require initial testing in humans in Phase 1 clinical trials. In order to ensure the capacity to evaluate the growing pipeline of investigational products as they become available, it is critical for DMID to establish the dedicated resources necessary to undertake Phase 1 clinical trials for a broad range of infectious diseases. This contract provides for the establishment and management of a Phase 1 Clinical Trial Unit for Therapeutics Against Infectious Diseases to fill this need.

SCOPE

The Contractor shall serve as the Phase 1 Clinical Trial Unit to assess the safety of investigational therapeutic products within the following scope:

1. **Scope of Infectious Diseases** - viral (other than HIV), bacterial, parasitic and fungal pathogens, including NIAID priority biodefense pathogens and emerging and re-emerging infectious diseases.

2. **Scope of Candidate Therapeutics** - new, untested investigational products, including novel immunomodulatory agents.

3. **Scope of Clinical Research** – Phase 1 clinical trials to determine safety, pharmacokinetics (pK) and pharmacodynamics (pD).

4. **Trial Populations** – healthy individuals, 18-45 years of age, drawn from the general population and including representatives of minority populations and both genders.

TECHNICAL REQUIREMENTS

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary facilities, qualified personnel, services, healthy volunteer populations, material, and equipment, not otherwise provided by the Government, as outlined below:

1. **CLINICAL RESEARCH FACILITIES, RESOURCES, AND STANDARD OPERATING PROCEDURES**

   a. Inpatient Clinical Research Facilities, Resources and Standard Operating Procedures

   Provide inpatient clinical research facilities for the implementation of approved protocols. These facilities shall include a Contractor-operated, "in-house" unit and units at affiliated clinical sites as necessary, each with the capacity to fully conduct a Phase 1 clinical trial at a single-site. These inpatient clinical research facilities shall meet the requirements of the Joint Commission on Accreditation of Healthcare Organizations (www.jcaho.org). Develop Standard Operating Procedures (SOPs) under which the facilities will operate. Inpatient clinical research facilities, resources and SOPs shall include:

   1) Clinical research facilities to accommodate overnight clinical care of subjects as specified in approved protocols, including the ability to quarantine subjects in isolation if necessary and for as long as necessary or until transported to an acute care facility. A minimum of 10 monitored inpatient beds is required for the Contractor's in-house unit and for all affiliated clinical sites.

   2) Standard clinical support services for inpatient care, 24 hours/day, 7 days/week, to include telemetry and ongoing capability to monitor other vital signs at frequent intervals, and nursing, emergency, respiratory, dietary, laboratory, radiology and laundry services for active inpatient protocols.

   3) Specialized testing facilities as specified in approved protocols, for example, respiratory physiological testing and specialized imaging tests.

   4) Computers with broadband secure internet access for randomization, remote data entry and transmission of digitalized test results, including electrocardiograms and other diagnostic test results and digital photographs.

   5) Services and facilities needed to stabilize subjects who require emergency care and to transfer them to an appropriate emergency care facility, as necessary, 24 hours/day, 7 days/week.

   6) SOPs for inpatient clinical research facilities:

      a) Within 30 calendar days of the effective date of the contract, provide, for Project Officer review and approval, draft SOPs governing the operations of the inpatient clinical research facilities.

b) Within 14 calendar days after receipt of and agreement on comments from the Project Officer, modify draft SOPs as necessary to incorporate Project Officer recommended revisions and provide final SOPs to the Project Officer, staff of the Contractor's in-house unit and staff of all affiliated clinical sites with outpatient clinical research facilities. Multiple rounds of review may be required. The final SOP is due within 90 calendar days from the effective date of the contract.

b. Outpatient Clinical Research Facilities, Resources and Standard Operating Procedures

Provide outpatient clinical research facilities at the Contractor's site and at all affiliated clinical sites to accommodate screening, enrollment and follow-up of subjects in accordance with the specific requirements of the protocols approved for implementation. Develop Standard Operating Procedures (SOPs) under which the facilities will operate. These outpatient clinical research facilities, resources and SOPs shall include:

1) Temporary waiting rooms and processing areas for check-in and discharge of subjects.

2) Examination rooms that allow for full physical examinations and privacy for discussions with subjects, including counseling and obtaining medical histories and informed consent.

3) Computers with secure broadband internet access for remote data entry and transmission of digitalized test results, including electrocardiograms and other diagnostic test results and digital photographs.

4) SOPs for outpatient clinical research facilities:

a) Within 30 calendar days of the effective date of the contract, provide, for Project Officer review and approval, draft SOPs governing the operations of the outpatient clinical research facilities.

b) Within 14 calendar days after receipt of and agreement on comments from the Project Officer, modify draft SOPs as necessary to incorporate Project Officer recommended revisions and provide final SOPs to the Project Officer, staff of the Contractor's in-house unit and staff of all affiliated clinical sites with outpatient clinical research facilities. Multiple rounds of review may be required. The final SOP is due within 90 calendar days from the effective date of the contract.

c. Clinical Laboratory Facilities, Resources, and Standard Operating Procedures

Provide the following clinical laboratory facilities and resources for inpatient and outpatient clinical trials conducted at the Contractor's site and at all affiliated clinical sites. Develop Standard Operating Procedures (SOPs) under which the facilities will operate. These clinical laboratory facilities, resources, and SOPs shall include:

1) Facilities for the processing and storage of clinical specimens and the conduct of protocol-required tests to determine subject eligibility and to conduct safety evaluations.

2) Qualified personnel and other resources necessary to maintain current Clinical Laboratory Improvement Amendment certification (www.cms.hhs.gov/clia) and Joint Commission on Accreditation of Healthcare Organizations approval.

3) Clinical laboratory support services, for example, centrifugation or liquid chromatography to fractionate samples that are available 24 hours/day, 7 days/week.

4) SOPs for clinical laboratory facilities and resources:

a) Within 30 calendar days of the effective date of the contract, provide, for Project Officer review and approval, draft SOPs governing the operations of the clinical laboratory facilities and resources.

b) Within 14 calendar days after receipt of and agreement on comments from the Project Officer, modify draft SOPs as necessary to incorporate Project Officer recommended revisions and provide final SOPs to the Project Officer, staff of the Contractor's in-house unit and staff of all affiliated clinical sites with outpatient clinical research facilities. Multiple rounds of review may be required. The final SOP is due within 90 calendar days from the effective date of the contract.

d. Research Laboratory Facilities, Resources, and Standard Operating Procedures

Provide the following research laboratory facilities and resources to service inpatient and outpatient clinical trials conducted at the Contractor's site and at all affiliated clinical sites. Develop Standard Operating Procedures (SOPs) under which the facilities will operate. These research laboratory facilities, resources and SOPs shall include:

1) Facilities for the processing and storage of clinical specimens and the conduct of protocol-specific tests to determine subject eligibility, baseline levels on entry into a trial, and safety follow up.

2) Qualified personnel and other resources necessary to maintain compliance with current SOPs.

3) Assurance that work conforms to standards acceptable for Investigational New Drug (IND), Biological Licensing Application (BLA) and/or New Drug Application (NDA) submission (see http://www.niaid.nih.gov/dmid/clinresearch/#resources for guidance).

4) SOPs for research laboratory facilities and resources:

a) Within 30 calendar days of the effective date of the contract, provide, for Project Officer review and approval, draft SOPs governing the operations of the research laboratory facilities and resources.

b) Within 14 calendar days after receipt of and agreement on comments from the Project Officer, modify draft SOPs as necessary to incorporate Project Officer recommended revisions and provide final SOPs to the Project Officer, staff of the Contractor's in-house unit and staff of all affiliated clinical sites with outpatient clinical research facilities. Multiple rounds of review may be required. The final SOP is due within 90 calendar days from the effective date of the contract.

e. Research Pharmacy Facilities, Resources and Standard Operating Procedures

Provide research pharmacy facilities and resources for the management of investigational products, according to protocol-specific requirements, to service inpatient and outpatient clinical trials conducted at the Contractor's site and at all affiliated clinical sites. Develop Standard Operating Procedures (SOPs) under which the facilities shall operate. These research pharmacy facilities, resources, and SOPs shall include:

1) Qualified personnel and other resources necessary to maintain compliance with current SOPs.

2) Facilities and resources for:

- receiving investigational products from the DMID Clinical and Regulatory Affairs Support contractor repository or other supplier;
- documenting and storing investigational products under appropriate conditions (e.g., specified temperature, humidity and other storage conditions);
- controlled access to investigational products;
- distributing investigational products to the clinical area; and
- returning investigational products to the supplier, or disposing of investigational products as directed by the Project Officer and specified in the approved protocol or Manual of Operations.

3) SOPs for research pharmacy facilities and resources:

a) Within 30 calendar days of the effective date of the contract, provide, for Project Officer review and approval, draft SOPs governing the operations of the research pharmacy facilities and resources.

b) Within 14 calendar days after receipt of and agreement on comments from the Project Officer, modify draft SOPs as necessary to incorporate Project Officer recommended revisions and provide final SOPs to the Project Officer, staff of the Contractor's in-house unit and staff of all affiliated clinical sites with outpatient clinical research facilities. Multiple rounds of review may be required. The final SOP is due within 90 calendar days from the effective date of the contract.

f. General Clinical Research Facilities, Resources, and Standard Operating Procedures

Provide general clinical research facilities and resources at the Contractor's site and at all affiliated clinical sites, and develop Standard Operating Procedures (SOPs) under which the facilities and resources will operate. These general clinical research facilities, resources, and SOPs shall include:

1) Non-clinical space for contract management, data management and trial coordination.

2) Computers with secure broadband internet access.

3) Adequate space for clinical site monitoring staff to include secure broadband internet access to site computers and access to regulatory and subject records.

4) Areas for secure storage of confidential trial documents with controlled access.

5) SOPs for general clinical research facilities and resources:

a) Within 30 calendar days of the effective date of the contract, provide, for Project Officer review and approval, draft SOPs governing the operations of the general clinical research facilities and resources.

b) Within 14 calendar days after receipt of and agreement on comments from the Project Officer, modify draft SOPs as necessary to incorporate Project Officer recommended revisions and provide final SOPs to the Project Officer, staff of the Contractor's in-house unit and staff of all affiliated clinical sites with outpatient clinical research facilities. Multiple rounds of review may be required. The final SOP is due within 90 calendar days from the effective date of the contract.

g. Insurance

The Contractor and all affiliated clinical sites participating in the conduct of approved protocols shall provide sufficient malpractice insurance and indemnification for trial-related injuries to subjects.

2. **SCIENTIFIC AND TECHNICAL PERSONNEL**

a. Principal Investigator

1) The Principal Investigator (PI) shall be licensed as a physician in the state of the Contractor's inpatient facility and shall ensure that active licensure is maintained for the entire period of contract performance. The PI shall also maintain licensure in the state of the Contractor's inpatient facility to dispense controlled dangerous substances and Drug Enforcement Agency (DEA) registration.

2) The PI shall possess experience and demonstrated competence in the design and conduct of Phase 1 clinical trials to determine safety and pK/pD of therapeutics. The PI shall also possess experience and demonstrated competence in managing multiple clinical sites.

b. Other Scientific/Technical Personnel

1) Provide and assure availability of a staff of appropriately trained personnel at the Contractor's site and at all affiliated clinical sites sufficient to carry out the clinical research requirements of the contract. This shall include:

a) A pharmacologist and pharmaco-toxicologist experienced in evaluating pre-clinical drug information and in the design of Phase 1 clinical trials to determine the safety and pK/pD of therapeutics.

b) Physician investigators as required per protocol. Physician investigators conducting clinical trials shall be physicians licensed in the state of the inpatient facility and shall ensure that active licensure is maintained for the entire period of contract performance. All such protocol-specific physician investigators shall possess experience and demonstrated competence in the design and conduct of Phase 1 clinical trials to determine the safety and pK/pD of therapeutics and experience in complying with Good

Clinical Practices (GCP), food and drug law (21 CFR 312), and other regulatory requirements governing the conduct of research involving human subjects. Further, qualified physician investigators shall be available 24 hours/day, 7 days/week while a protocol is on-going.

c) Qualified, licensed personnel able to perform emergency life-saving procedures if necessary, to be available 24 hours/day, 7 days/week while a trial is on-going.

d) Clinical research staff as required per protocol, including: nurse managers, nurses, physician assistants, trial coordinators, clinical support staff, laboratory personnel, personnel with regulatory expertise, data managers, and data entry personnel. All clinical research staff shall be licensed as appropriate and experienced in complying with GCP, food and drug law (21 CFR 312), and other regulatory requirements governing the conduct of research involving human subjects.

e) A licensed Research Pharmacist and pharmacy staff proficient in all aspects of investigational product management as needed to meet the requirements of each protocol.

f) Collaborating clinical investigators in other medical specialties, when necessary to meet protocol-specific requirements.

g) Qualified personnel necessary to package, label, inventory and transport under appropriate conditions clinical specimens to DMID-designated laboratories or DMID-supported repositories in cases where laboratory tests are not to be performed at the Contractor's facility or at affiliated clinical sites.

h) Qualified personnel, such as microbiologists with specialized expertise, necessary for the final preparation of investigational products in accordance with protocol-specific requirements.

i) A statistician experienced in clinical trial design and analysis and assay development/validation.

3. **AFFILIATED CLINICAL SITES (SUBCONTRACTORS)**

Solicit and evaluate proposals and award and manage subcontracts to provide for affiliated clinical sites when necessary and appropriate to meet the requirements of the contract. All subcontracts shall be consented to in writing by the Contracting Officer based on review and recommendation of the Project Officer, prior to subcontractor protocol implementation.

a. Affiliated clinical sites shall be used at the Contractor's discretion for one or more of a variety of purposes in order to carry out the requirements of the contract. Such purposes include:

1) Providing access to and ensuring full enrollment of subjects within 90 calendar days of protocol implementation, unless otherwise specified in the approved protocol.

2) Fully enrolling and conducting clinical trials upon approval of the Project Officer.

b. Ensure that all affiliated clinical sites provide the personnel, facilities and services as noted in paragraphs 1. and 2., above.

4. **TRIAL POPULATION AND ENROLLMENT REQUIREMENTS**

a. Provide subjects from the healthy population (18-45 years of age), including members of minority populations and both genders, sufficient to recruit and enroll a minimum of 150 individuals annually, utilizing subcontracts with affiliated clinical sites as necessary.

b. Provide for enrollment of appropriate subjects within 90 calendar days of implementing the approved protocol, utilizing affiliated clinical sites, as necessary.

c. DMID reserves the right to pre-approve all screened subjects prior to administration of the trial investigational product based on review by the Project Officer of the anonymous screening results of the recruited subjects.

5. **PROTOCOL DEVELOPMENT**

a. Concept Proposal

1) Develop a Concept Proposal with a corresponding budget estimate for each proposed clinical trial as the initial step in the protocol development process. The development and submission of Concept Proposals and corresponding budgets shall be at the request of the Project Officer, who will provide the necessary pre-clinical information package and a written request for the preparation of a Concept Proposal. All Concept Proposals shall be submitted to the Project Officer for review within 14 calendar days of receipt of the request and must be approved in writing by the Project Officer prior to initiation of protocol development.

2) The Concept Proposal shall include:

a) Trial Objective(s)

(1) indication(s) of the investigational product and stage of development,
(2) definition of the trial population,
(3) a brief overview of the proposed trial design, including justified estimated sample size, primary and secondary endpoints, and investigational product information, including available risk information, and
(4) the stage of development of the proposed assays to be used to support the primary and secondary endpoints.

b) Rationale for the Proposed Clinical Trial

(1) a brief description of the scientific and public health significance of the proposed trial and supporting references.

c) Recruitment and Site Plan

(1) a plan for the recruitment and retention of eligible subjects,
(2) target enrollment for the proposed clinical site, including documentation of access to trial populations,
(3) identification and physical depiction of the proposed clinical site at which the trial will be conducted, and
(4) a site plan indicating the capacity of the clinical site to undertake and complete the trial successfully.

d) Protocol Timeline

A timeline and specific milestones for:

(1) development of final protocol,
(2) study initiation,
(3) completion of screening and enrollment of subjects,
(4) completion of the clinical trial, and
(5) analysis of final trials data.

In general, it is expected that each protocol will be recruited and completed (when the last subject is enrolled and has completed the first visit) within 90 calendar days from the first day of recruitment.

e) Personnel and Percentage of Effort

A list of all personnel who will be assigned to the clinical trial, including:

(1) percentage of effort for each,
(2) a description of prior experience and expertise of the personnel specific to the proposed clinical trial, and
(3) prior experience with trials of a similar type, size and complexity.

f) Proposed Budget

(1) A breakdown of proposed trial-specific personnel by:

(a) function,
(b) position title, and
(c) level of effort.

(2) Total estimated costs for:

(a) inpatient care,
(b) outpatient care,
(c) supplies,
(d) clinical and research laboratory,
(e) research pharmacy,
(f) subject expenses,
(g) subject incentives,
(h) travel for physician investigators and subjects,
(i) advertising costs only as they relate to recruitment from existing patient population databases, and
(j) miscellaneous cost

b. Protocol Development

1) Protocol Development Processes and Templates

In developing protocols for clinical trials to be conducted under this contract, the Contractor shall adhere to DMID standardized protocol development processes and templates (http://www.niaid.nih.gov/dmid/clinresearch/#resources). Only those Concept Proposals approved for implementation by the Project Officer shall proceed to the protocol development stage. The processes and requirements delineated below shall be implemented by the Contractor during the protocol development stage. All final Protocols require approval by the Project Officer in order to proceed to the protocol implementation stage.

2) Protocol Team

Each protocol shall be developed by a Protocol Team, coordinated by the Project Officer and/or a DMID Program Officer with expertise in the area of protocol focus and designated by the Project Officer. The Protocol Team shall consist of:

a) the Principal Investigator,
b) clinical investigators from the clinical site at which the Phase 1 trial is being performed,
c) other experts or consultants as needed,
d) industry collaborators, when appropriate, and
e) DMID scientific, clinical and regulatory personnel.

3) Draft and Final Protocol

a) Within 30 calendar days of Concept Proposal approval, develop the Draft Protocol for Project Officer review, with assistance from the Protocol Team, and make any necessary revisions based on comments provided by the Project Officer and other assigned DMID staff.

b) If revisions to the Protocol are requested by the Project Officer, each revised Draft Protocol shall be provided for Project Officer review within 14 calendar days of receipt of the Project Officer's comments by the Contractor.

c) The protocol shall be considered final only upon receipt of written approval from the Project Officer.

4) Development of Trial-related Documents

a) In parallel with protocol development, develop trial-related documents, including: the Informed Consent Form, Case Report Forms, Manual of Operations, source documents, questionnaires, memory aids, subject instructions, screening and recruitment logs, order forms for clinical supplies and test articles, and test article accountability logs.

b) Provide all trial-related documents to the Project Officer for review and approval within 21 calendar days of receipt of written Project Officer approval of the Final Protocol.

c) Trial-related documents shall be considered final only upon receipt of written approval from the Project Officer.

5) Protocol Timeline Modifications

a) If necessary, propose revisions to the Protocol Timeline provided in the Concept Proposal [paragraph 5.a.2) d), above] to accommodate any changes with respect to protocol implementation, trial completion and analysis of trial results, including the rationale for the proposed changes.

b) All such modifications to the Protocol Timeline shall be subject to written approval by the Project Officer prior to trial implementation.

6. PROTOCOL IMPLEMENTATION

a. Pre-Trial Initiation Requirements

Prior to trial initiation, the Contractor shall satisfy the following requirements:

1) Human Subjects Requirements

Obtain and provide to the Project Officer documentation of the Institutional Review Board (IRB) approval to conduct the clinical trial for all participating clinical sites. Each clinical site should possess an Office of Human Research Protection (OHRP) Federal Wide Assurance (FWA) number. The use of the proposed IRB must be pre-approved by the Project Officer.

2) Regulatory Requirements

Provide, for Project Officer approval, Essential Documentation, as defined by the International Conference on Harmonization ICH-E6-GCP, (http://www.fda.gov/cder/guidance/959fnl.pdf).

3) Trial Initiation Meetings/Teleconferences

The Principal Investigator, clinical investigators, clinical trial personnel who will be performing the clinical trial, and other experts and consultants, as needed, shall participate in face-to-face meetings and/or teleconferences to initiate each trial to be organized by the clinical site monitoring team for each trial (SOW 7.c). These meetings and/or teleconferences shall serve to review information pertinent to the conduct of the trail, including protocol specifications, requirements and procedures, target enrollment and protocol timelines.

4) Trial Investigational Product Requirements

The Principal Investigator shall provide documentation that all participating clinical sites have received the appropriate supply of the investigational product from the DMID Clinical and Regulatory Affairs Support contractor repository or other entity within 7 calendar days of the request by the Project Officer. This shall encompass investigational product accountability, including:

a) accurate records documenting receipt of test article,
b) date and amount of test article dispensed to each subject,
c) amount of test article used and verified during a monthly physical inventory,
d) date and quantity of test article returned to DMID repository or other entity, if applicable,

e) preservation and validation of cold chain for investigational and licensed products including records to verify cold chain for all materials stored at other than room temperature,
f) packaging and labeling of test article in compliance with applicable labeling regulations, and
g) transport of investigational products to clinical area.

b. Interactions with Food and Drug Administration (FDA)

For each protocol, the Principal Investigator shall be available for up to 6 teleconferences and 1 meeting with the FDA to discuss protocols, preclinical and clinical information, and/or data resulting from trials as needed.

c. Clinical Trial Conduct

Clinical trials shall be conducted in accordance with all Federal regulations, food and drug laws and all applicable regulations, NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf), the ICH-E6-GCP guidelines (http://www.fda.gov/cder/guidance/959fnl.pdf), the Protocol and the Manual of Operations or standard operating procedures.

d. Protocol Amendments and Other Clinical Trial Modifications

1) Provide, to the Project Officer, a written description of and the rationale for recommended amendments/modifications to the Final Protocol, the Manual of Operations and the informed consent documents.

2) All amendments/modifications require written approval by the Project Officer prior to implementation.

3) Obtain and provide to the Project Officer documentation of IRB approval for protocol amendments/modifications for all participating clinical sites.

7. PROTOCOL OVERSIGHT

Oversee and ensure adherence to all Federal regulations, food and drug laws and all applicable regulations, and to the DMID, NIAID, NIH policies and guidelines, including the NIAID Clinical Terms of Award, governing research involving human subjects (http://www.niaid.nih.gov/dmid/clinresearch) for clinical trials conducted by the Contractor and by all affiliated clinical sites. This shall include responsibility for the safety of subjects, overseeing the conduct of all clinical trials, including those conducted at affiliated sites, coordinating safety oversight responsibilities and functions in collaboration with the DMID Clinical Trials Management (CTM) contractor and with protocol-specific Safety Oversight Structures, as delineated below.

a. Safety Oversight Structure

1) For each clinical trial, DMID will establish a Safety Oversight Structure, independent of the Principal Investigator and coordinated by the CTM contractor. All Safety Oversight Structures shall operate in a manner consistent with DMID Safety Oversight Guidances (http://www.niaid.nih.gov/dmid/clinresearch/). The Contractor shall be responsible for presenting the protocol and trial data at meetings and teleconferences of the Safety Oversight

Structures and shall be available to answer questions both during and after such meetings/teleconferences.

2) The Safety Oversight Structure will be determined by DMID based on the risk and complexity of the clinical trial. For most Phase 1 clinical trials, the Safety Oversight Structure shall be a Safety Monitoring Committee (SMC). However, for clinical trials for which the risks and complexities are justified, the Safety Oversight Structure shall be a Data and Safety Monitoring Board (DSMB). In all cases, the DSMB or the SMC shall be established by DMID and coordinated by the CTM contractor.

3) All trials shall be overseen by an Independent Safety Monitor and designated back-up monitor independent of the clinical site and identified by the Contractor and approved by the Project Officer.

4) At the Project Officer's request, nominate individuals to serve on Safety Oversight Structures. Appointment to Safety Oversight Structures requires approval by the Project Officer based on DMID Safety Oversight Guidances (http://www.niaid.nih.gov/dmid/clinresearch/).

5) Provide both interim and final safety analyses in the requested timelines as specified in the protocol or requested by the Safety Oversight Structure.

b. Clinical Site Assessment

1) Clinical site assessment shall be performed for each clinical site by the CTM contractor prior to initiation of a protocol.

2) Make available, for the purpose of assessing clinical sites, all necessary facilities, personnel and records to support site assessment requirements prior to the active recruitment phases of all clinical trials.

c. Clinical Site Monitoring

When DMID is the IND sponsor, the Contractor shall perform clinical site monitoring for all clinical trials conducted by the Contractor and affiliated clinical sites. When DMID is not the IND sponsor, the IND sponsor may designate appropriate monitoring staff to perform this function or delegate this responsibility to the Contractor. Specifically, the Contractor shall:

1) Provide an independent Clinical Site Monitoring Team to verify that the rights and well-being of the subjects are protected, the trial data are accurate, complete and verifiable, and the conduct of the trial is in compliance with GCP, the approved protocol and applicable regulatory requirements. The Clinical Site Monitoring Team shall be independent of the Contractor and all affiliated clinical sites and shall be responsible for:

a) *Clinical Site Monitoring Plan Template:* Developing and implementing a Clinical Site Monitoring Plan Template detailing monitoring activities and requirements. The Draft Clinical Site Monitoring Plan Template shall be submitted for review by the Project Officer within 30 calendar days of the effective date of the contract, revised as necessary based on Project Officer comments, and finalized within 14 days of receipt of Project Officer comments.

b) *Clinical Site Monitoring Plan*: Developing and implementing a Clinical Site Monitoring Plan that details monitoring requirements and activities for each protocol. The Draft Clinical Site Monitoring Plan shall be submitted for Project Officer review within 14 calendar days of the approval date of each protocol, revised as necessary based on Project Officer comments within 7 calendar days of receiving comments, and finalized.

c) *Clinical Site Monitoring Visits and Reports:* Conducting clinical site monitoring visits and providing to the Project Officer, within 14 calendar days of site visit completion, a Clinical Site Monitoring Report detailing the findings of each visit, including deficiencies, performance problems, and recommended corrective actions.

2) Make available, for the purpose of clinical site monitoring, all necessary facilities, personnel and records to support monitoring requirements during the active recruitment, dosing, follow-up and close-out phases of all clinical trials for the Contractor and all affiliated clinical sites.

3) Develop and implement corrective actions to address site performance problems and issues identified through the clinical site monitoring process. These actions must be approved by the Project Officer prior to implementation.

d. System of Records

Design, implement and maintain a system of records for each clinical trial undertaken. This system of records shall be in accordance with the Privacy Act and the Confidentiality of Information Clauses contained within the contract.

8. **DATA MANAGEMENT AND QUALITY CONTROL**

a. Provide, maintain and operate a data management and quality control system with the following features:

1) Ability to receive, enter, verify, label, process, edit (including within and across form validity, logic, and consistency checks), update, correct, freeze, lock, store, secure, track, and retrieve all clinical and laboratory data at a central data management facility.

2) Compliance with all current Federal regulations (21 CFR 11 and/or similar regulations, http://www.fda.gov/cber/guidelines.htm; http://www.fda.gov/cder/guidance/; and meet current globally-accepted standards, including ICH E-2 (A,B and C), Clinical Safety Data Management and ICH M-5, Data Elements and Standards for Drug Dictionaries (http://www.ich.org/cache/compo/475-272-1.html and http://www.ich.org/cache/compo/2196-272-1.html, respectively).

3) Computerized trial forms and systems for data entry and transmission of subject data from clinical sites and laboratories.

4) Real-time electronic notification of appropriate DMID personnel, i.e. Project Officer and Medical Officers, in the event data trigger halting rules.

5) Provision of real-time data access for appropriate DMID personnel, i.e. Project Officer and Medical Officers, utilizing a secure, password protected internet connection.

6) Ability to evaluate quality assurance data generated in connection with the clinical trials.

7) Ability to address queries in accordance with DMID source document guidelines (www.niaid.nih.gov/dmid/clinresearch/sourcedocumentationstandards.pdf), or the guidelines of the data management center of an industry collaborator.

8) Security against anticipated risks, including loss of confidentiality of subject electronic records and data summaries, and catastrophic loss of trial data or important software, including an off-site secured storage facility for system back-ups.

   a) References for system security information and guidance are located in Section H of the contract at the end of the Article entitled "Information Security."

   b) A System's Security Plan (SSP), which minimally shall include the Risk Analysis (RA) and the Continuity of Operations Plan (COOP -- also known as the Contingency Plan).

   c) The preparation and submission of an annual Information System Security Plan (ISSP), following the instructions in the HHS SecureOne Policy http://intranet.hhs.gov/infosec/about.html, for review and approval by the Project Officer and the NIAID Information System Security Officer (ISSO).

   d) A log or record of the results from testing the COOP, any existing plans and progress reports for implementing additional security safeguards and controls, and the system access authorization list. The profile shall be kept up-to-date for review and potential inspection upon demand by NIH/DHHS authorized agents. Upon request, copies of specified profile documents shall be presented to NIH/DHHS for its own system's security reporting requirements.

   e) The preparation and submission, for Project Officer approval, of a RA following the guidance given in the HHS SecureOne Policy. The RA is to be maintained and updated every three years, or in advance of implementing major system modifications or enhancements.

   f) The development and maintenance of an up-to-date COOP following the guidance in the HHS SecureOne Policy. At a minimum, the COOP shall cover emergency operations, backup operations, and recovery plans to assure continuous operations of the system's facility. COOP testing shall be conducted and the results recorded at least every six months.

   g) Plans, procedures and a recommended schedule and budget for implementation of security safeguards required to satisfy the anticipated conditions of acquiring data from the clinical and laboratory sites. This includes data integrity and security during electronic transmission or during transit from the study sites to the SDCC if non-electronic data transmission is used. All subject identifiable data is subject to the Privacy Act, Health Insurance Portability and Accountability Act (HIPAA) and DHHS regulations.

9) For a site with intermittent internet connection, provide a system for off-line data entry. Data may be transmitted at a later time when internet connection is available.

10) For a site with unreliable electrical power, implement alternate power source, back-up systems and/or contingency plans.

b. Develop and implement standards and procedures for the entry and quality control of trial data for all clinical trials conducted under the contract, including those conducted at affiliated clinical sites.

c. Ensure that clinical data are accurate, complete and entered in a timely fashion.

d. Transfer trial data from the Contractor-operated and all affiliated clinical sites to the data management system within 72 hours of trial activity to maintain up-to-date information on all clinical and laboratory data.

e. Provide training in the use of the data management system for clinical site personnel and DMID personnel prior to trial implementation.

f. Address queries in accordance with DMID source document guidelines (www.niaid.nih.gov/dmid/clinresearch/sourcedocumentationstandards.pdf), or the data management center of an industry collaborator.

g. Upon approval of the Project Officer, provide clinical trial data to the DMID for use in the Annual IND Report to the FDA. The Principal Investigator and the Protocol Team shall collaborate in the analysis of final trial data, including submission, receipt, collation and interpretation of the trial data. Prepare the Final Clinical Trial Report which shall follow the International Conference on Harmonization (ICH) Guidelines on Structure and Content of Clinical Trial Reports E3 to be submitted to the FDA by DMID (link for annual report: http://a257.g.akamaitech.net/7/257/2422/01apr20051500/edocket.access.gpo.gov/cfr_2005/aprqtr/21cfr312.23.htm and link for final report: http://a257.g.akamaitech.net/7/257/2422/01apr20051500/edocket.access.gpo.gov/cfr_2005/aprqtr/21cfr312.64.htm). The Final Clinical Trial Report should be provided to the Project Officer no later than 90 calendar days following receipt of the final trial analysis data.

9. STORAGE, SHIPPING AND TRACKING OF CLINICAL SPECIMENS

a. Provide adequate facilities for temporary storage of clinical specimens.

b. Ship clinical specimens for further testing to laboratories and/or repositories designated by the Project Officer.

c. Ensure that blood and other body fluids and tissue samples are classified, labeled, documented, packaged, shipped, and tracked according to Federal regulations and the International Air Transport Association (IATA) requirements for the shipment of dangerous goods (http://www.iata.org/ps/publications/9065.htm).

d. Ship samples under temperature monitored conditions and within the time frame specified in the approved protocols and/or other trial-related documents.

e. Confirm receipt of clinical specimens in the appropriate condition for further testing by the DMID-designated laboratory or for storage.

10. QUALITY ASSURANCE/QUALITY CONTROL (QA/QC)

a. Quality Assurance/Quality Control Plan

1) The Contractor shall develop and implement a Quality Assurance/Quality Control plan to standardize contract research processes to ensure that the conduct of any clinical trial and all data generated meet all regulatory standards and other standards (see http://www.niaid.nih.gov/dmid/clinresearch/OP_QM001Rev0.pdf for guidance). This plan shall include SOPs for establishing and maintaining the QA/QC process. It shall also include a description of the process for internal quality audits of site protocols and a description of remediation procedures for addressing issues when identified.

2) Submit Draft QA/QC Plan to Project Officer within 90 calendar days of the effective date of the contract.

3) The Project Officer will provide comments to the Contractor within 14 calendar days of receipt of the Draft QA/QC Plan.

4) Submit a Final QA-QC Plan that incorporates the Project Officer's comments within 14 calendar days after Project Officer comments are received.

b. Independent Audits

1) Arrange for independent audits, as needed or as requested by the Project Officer with concurrence of the Contracting Officer. Audits may be requested to assure that Contractor and/or affiliated clinical site facilities and all planned procedures meet FDA regulations and guidance for GCP standards.

2) Ensure that all Contractor and/or affiliated clinical site records and staff are available for independent audits.

3) Provide interim audit and final audit reports to the Project Officer and the Contracting Officer within 30 calendar days after completion of each respective audit.

11. PROJECT MANAGEMENT

a. Overall Project Management

1) Provide for the overall management, integration and coordination of all contract activities, including the management and coordination of activities carried out under subcontracts.

2) Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, management and timely completion of all projects carried out under this contract and effective communications with the Project Officer and the Contracting Officer.

3) Designate a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors. This individual shall comply with the requirements set forth in paragraph 2.a., above, of the SOW.

4) Provide personnel to coordinate contract and trial specific activities and administrative staff with responsibility for financial management and financial reporting on all activities conducted by the Contractor and subcontractors.

b. Subcontract Management and Reporting

1) Solicit, evaluate, award and manage subcontracts, including overseeing the technical, administrative and operational activities of subcontractors; audit subcontractor facilities, services, and financial expenditures; and track deliverables and reporting requirements.

2) Assess and provide Quarterly Technical Reports on subcontractor performance and progress toward achievement of defined tasks and responsibilities within established timelines; and identify and resolve problems with subcontractor performance.

3) Ensure that subcontractor personnel, equipment and facilities are compliant with regulatory requirements in effect throughout the contract period of performance.

4) Ensure the complete and effective transfer of any technology with potential for intellectual property, if developed, by the subcontractors to the Contractor, the United States Government, or a third party designated by the Project Officer.

5) Perform all necessary transition and closeout functions on each subcontract as specified in each protocol.

c. Coordination with DMID Clinical Research Support Services Contracts

Ensure the effective and efficient coordination of specified functions in collaboration with the DMID clinical research support services contractors. These functions include:

1) safety monitoring, oversight and pharmacovigilance,
2) auditing,
3) distribution and tracking of IND products from the clinical agent repository,
4) collaboration with the DMID CTM contractor to facilitate study implementation, assess study progress and evaluate processes and procedures with respect to the following activities:
   a) site assessments, comparison and reconciliation of the clinical Adverse Event (AE) database with the pharmacovigilence (PVG) Serious Adverse Event (SAE) database;
   b) reporting on halting rules;
   c) Safety Oversight Structure reporting; and
   d) study site-specific reporting.
5) collaboration with the DMID Clinical and Regulatory Affairs Support contractor with respect to specimen tracking and inventory.

d. Meetings

1) Contract Initiation Meeting

Within 60 calendar days of the effective date of the contract, the Principal Investigator, pharmaco-toxicologist, pharmacologist and other key personnel, as determined by the Principal Investigator and agreed upon by the Project Officer, shall participate in a one-day contract initiation meeting with the Project Officer, the Contracting Officer, and other key

NIAID staff, to be held in the Bethesda, Maryland area. The purpose of this initiation meeting is to orient the Contractor to NIAID contract procedures.

2) Site Initiation Meetings

Within 180 calendar days of the effective date of the contract, the Principal Investigator, in collaboration with the Project Officer, shall arrange for a meeting at the Contractor-operated site and each participating subcontractor-operated site, to be attended by all staff of the individual Contractor- or subcontractor-operated site, the Project Officer, and other NIAID staff as determined by the Project Officer. The Principal Investigator shall attend the meeting at the Contractor's site. The Project Officer will develop the agenda. The purpose of these site initiation meetings is for Contractor and subcontractor personnel and DMID staff to establish lines of communication and to review NIAID guidelines and operating procedures. No subjects shall be enrolled in any Phase 1 clinical trial at any participating site until this meeting had occurred.

3) Annual Meetings

Key Contractor and subcontractors personnel shall participate in 1 meeting per year for 2 days, to be held in the Bethesda, Maryland area. The purpose of these meetings is to:

a) organize, facilitate and plan clinical trials and trial coordination;
b) address regulatory issues related to clinical trials proposed and approved for implementation; and
c) review the status of ongoing clinical trials, risks and obstacles, proposed approaches to reducing risk and overcoming obstacles, and interim and final clinical trial results.

4) Annual Site Visits

a) Host an annual site visit for NIAID contract and program staff. These site visits shall be attended by the Principal Investigator, the Contractor's business representative, all key personnel and investigators and coordinators of active trials from the previous twelve months, including personnel from affiliated clinical sites.

b) The Contractor shall be responsible for:

1) agenda planning, subject to approval by the Project Officer,
2) development of written and oral presentation materials, and
3) logistical arrangements and travel costs for all non-Government Site Visit participants.

c) Presentations and discussions shall focus on:

1) summaries of all goals and milestones reached during the review period;
2) all problems encountered that impact the completion of approved clinical trials;
3) the submission of contract deliverables;
4) proposed modifications to established timelines; and
5) proposed future plans for effectively and efficiently carrying out the requirements of the contract.

d) Annual Site Visit Reports shall be prepared and submitted to the Project Officer and the Contracting Officer within 30 calendar days of completion of each site visit.

5) Protocol Specific Meetings

The Principal Investigator, clinical investigators, trial coordinator and other key personnel, as determined by the Principal Investigator, the Project Officer and other DMID staff shall participate in trial initiation meetings, Protocol Team meetings, and scientific planning meetings, as needed. These meetings may be conducted in person in the Bethesda, Maryland area, web-based or via teleconference.

e. Publications and Presentations of Contract-Generated Data and Findings

1) Develop and implement policies and procedures for authorship, preparation, review, and final approval of publications, abstracts and oral presentations resulting from contract-sponsored trials, and for submission of manuscripts for publication in peer reviewed journals. During the publication review and approval process, the respective roles and responsibilities of pharmaceutical/biotechnology companies providing experimental investigational products for evaluation in clinical trials shall be addressed in specific Clinical Trial Agreements (CTA) between DMID and the company.

2) The Contractor shall not publish, present or disseminate any information from work performed under this contract without prior submission of the materials to the Project Officer for review.

3) The Project Officer or designee will have 7 calendar days from receipt of materials to review and provide comments on an abstract, and 30 calendar days from receipt of materials to review and provide comments on other publications and presentations. If the Project Officer does not respond within these time frames, the Contractor may proceed with such publications or presentations.

12. **TRANSITION**

a. Transition Plan

No later than 180 calendar days prior to the completion date of this contract, provide a plan for the orderly, safe and efficient transition of contract-generated data and materials, including stored clinical specimens and subject records, to the Government or other Government designee. This plan shall be subject to approval by the Project Officer and the Contracting Officer.

b. Transition of Data and Materials

On or before the completion date of the contract, deliver data and materials, including clinical specimens and subject records, to locations specified by the Project Officer and in accordance with the approved transition plan.

[END OF STATEMENT OF WORK]

REPORTING REQUIREMENTS AND DELIVERABLES

Phase 1 Clinical Trial Unit for Therapeutics Against Infectious Diseases
RFP NIH-NIAID-DMID-08-06

ARTICLE C.2. REPORTING REQUIREMENTS

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of this contract.

All reports shall be submitted in an electronic format approved by the Project Officer. In addition, two (2) hard copies shall be submitted to the Project Officer and one (1) hard copy shall be submitted to the Contracting Officer. Electronic files shall be sent by e-mail or on computer discs (CD) by U.S. mail or a shipping service that provides tracking.

Format of Cover Page for each Report

All reports shall include a cover page prepared in accordance with the following format:

- Contract Number and Project Title
- Period of Performance Being Reported
- Contractor's Name and Address
- Author(s)
- Date of Submission
- Delivery Address

A. Monthly Expenditure Report

The Contractor shall submit Monthly Expenditure Reports with the first report covering the period consisting of the first full calendar month and any fractional part of the initial month following the effective date of the contract. Thereafter, reports are due on or before the 30th of the month following each reporting period.

The Monthly Expenditure Report shall include cumulative spending for each protocol as well as a breakdown of expenditures for each protocol, including: personnel (number of hours expended for each trial and cumulative overall), fringe benefits, consultants (identify specific protocol and role), materials and supplies, equipment (specify), staff travel (identify protocol and purpose of travel), and other direct costs.

B. Bi-monthly Technical Progress Report

The Bi-Monthly Technical Progress Report shall provide a description of the activities undertaken during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of every two months. Reports are due on or before the 30th of the month following each reporting period. The Bi-monthly Technical Progress Report shall not be due when the Semi-annual Technical Progress Report is due.

This Report shall include a line listing of all trials, identified by study number, in which the Contractor is actively engaged. The report shall be organized according to the following categories of clinical trials:

a. trials in development,
b. trials open and enrolling,
c. trials in follow-up, and
d. closed trials with analytic and report activities in progress.

Fields shall capture study number, sample size (n=), PI, assigned Contractor staff, clinical sites or expected number of sites, and comment fields for study status and/or action items. The Report shall also identify any problems encountered for subsequent discussion with the Project Officer.

C. Quarterly Subcontractor Technical Progress Report

The Quarterly Technical Progress Report shall provide a description of the activities undertaken by each subcontractor during the reporting period and the activities planned for each subcontractor during the ensuing reporting period. The first reporting period consists of the first full quarter of performance plus any fractional part of the initial quarter. Thereafter, the reporting period shall consist of every three months. Reports are due on or before the 30th of the month following each reporting period. The Quarterly Technical Progress Report shall not be due when the Semi-annual Technical Progress Report is due.

The report shall include:

1. Table of Contents
2. Progress toward achievement of each defined task within established timelines
3. Identification of issues and problems, their resolution or proposed approaches for resolution and estimated costs for resolution
4. Any additional information pertinent to contract performance

D. Semi-annual Technical Progress Report

The Contractor shall submit a Semi-annual Technical Progress Report, which summarizes the activities in progress and completed in the preceding 6 months. The initial report will be submitted for the first full 6 months of the contract performance period including any fractional part of the initial month. Thereafter, the reporting period shall consist of 6 full calendar months. The Semi-annual Technical Progress Report is due the 30th of the month following each 6- month performance period and shall include:

1. Table of Contents
2. Summary of work performed for each protocol
3. Identification of issues and problems, their resolution or proposed approaches for resolution and estimated costs for resolution
4. Any additional information pertinent to contract performance

A Semi-annual Technical Progress Report is not due when the Annual Technical Progress Report or Final Report is due.

E. Semi-annual Research Laboratory Report

The Contractor shall submit a Semi-annual Laboratory Report that includes all laboratory work performed to support clinical trials, laboratory work performed at the request of the Project Officer. The Semi-annual Technical Progress Report is due the 30th of the month following each 6-month performance period and shall include:

1. Table of Contents
2. Summary of work performed for each protocol
3. Identification of issues and problems, their resolution or proposed approaches for resolution and estimated costs for resolution
4. Any additional information pertinent to contract performance

A Semi-annual Laboratory Report is not due when the Annual Technical Progress Report or Final Report is due.

F. Annual Technical Progress Report

The Contractor shall submit an Annual Technical Progress Report, which summarizes the activities in progress and completed in the preceding 12 months. The Annual Technical Progress Report is due the 30th of the month following each anniversary date of the contract and shall include:

1. Table of Contents
2. Summary of work performed for each protocol
3. Identification of issues and problems, their resolution or proposed approaches for resolution and estimated costs for resolution
4. Any additional information pertinent to contract performance

An Annual Technical Progress Report shall not be not due when a Final Report is due.

G. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in SECTION J of this contract. The contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report.

The contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract. Thereafter, the report shall be due on or before the 30th of the month following each reporting period. The final report shall be due on or before the completion date of the contract.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October 2001, applies. If this contract is for Phase 3 clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the

final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

H. Final Report

1. Draft Final Report: A draft of the Final Report is due 180 calendar days prior to the completion date of the contract. The Project Officer will provide comments back to the Contractor within 14 calendar days of receipt of the Draft Final Report. Following discussion and agreement on the incorporation of recommended revisions, the Contractor shall submit the Final Report to the Project Officer's 90 calendar days before the completion date of the contract.

2. Final Report: The Final Report shall describe all work performed and results obtained for the entire contract period of performance. The final report shall include final analyses of the data on sex/gender and race/ethnicity. This report shall be in sufficient detail to describe comprehensively the results achieved. The Contractor shall submit, with the Final Report, a Summary of Salient Results (not to exceed 200 words) achieved during the performance of the contract.

I. Other Reports and Deliverables

In addition to the above reports, other reports and deliverables are identified in the Statement of Work. A listing is included in Article F.1., Deliveries.

ARTICLE F.1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract. will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract:

If the Contractor is unable to deliver the reports specified hereunder by the required due date because of unforeseen difficulties notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Project Officer and Contracting Officer immediate advance written notification of the anticipated delays with reasons, therefore, and a proposed revised due date. The revised due date must be acceptable to both the Project Officer and Contracting Officer. Copies of the technical reports shall be submitted as follows:

Satisfactory performance of the contract is defined as satisfactorily performing the statement of work and delivering the following items.

A. Technical Reports Delivery Schedule

Item	Type of Report	Recipients	Delivery Schedule
1.	Monthly Expenditure Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Due within 30 calendar days following the completion of each reporting period.
2.	Bi-Monthly Technical Progress Report	1 hard copy to PO 1 original to CO 1 elec. Copy to PO and CO	The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Due within 30 calendar days following the completion of each reporting period. Not due when a Semi-Annual Technical Progress Report is due.
3.	Quarterly Subcontractor Technical Report	1 hard copy to PO 1 original to CO 1 elec. Copy to PO and CO	The first reporting period consists of the first full quarter of performance plus any fractional part of the initial quarter. Due within 30 calendar days following the completion of each reporting period.
4.	Semi-Annual Technical Progress Report	1 hard copy to PO 1 original to CO 1 elec. Copy to PO and CO	Due on/before the 30th of the month following each 6-month period. Not due when an Annual or Final Report is due.
5.	Semi-annual Laboratory Report	1 hard copy to PO 1 original to CO 1 elec. Copy to PO and CO	Due on/before the 30th of the month following each 6-month period. Not due when an Annual or Final Report is due.
6.	Annual Technical Progress Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	Due on/before the 30th of the month following each anniversary date of the contract. Not due when the Final Report is due.
7.	Annual Utilization Report	1 copy to CO	Due on/before the 30th of the month following each anniversary date of the contract.
8.	Final Invention Statement	1 copy to CO	Due on/before completion date of the contract.
9.	All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification	1 copy to OPERA	As required by FAR Clause 52.227-11.

Item	Type of Report	Recipients	Delivery Schedule
10.	Draft Final Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	Draft Final Report is due 180 calendar days prior to the completion date of contract.
11.	Final Report and Summary of Salient Results	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	Final Report is due 90 calendar days prior to the completion date of the contract.

B. Other Reports and Deliverables Delivery Schedule

Item	Type of Deliverable	SOW Reference	Due	Recipient	Subsequent Deliverables Due
1.	Standard Operating Procedures (SOPS)	1.a.6 1.b.4 1.c.4 1.d.4 1.e.3 1.f.5	Draft SOPs: due 30 calendar days after effective date of contract. Final SOPs: due 90 calendar days after effective date of contract.	PO	Revisions to be submitted to the PO 14 calendar days following receipt of comments
2.	Concept Proposals	5.a	14 calendar days following request by the PO	PO	N/A
3.	Trial Protocols	5.b	30 calendar days following concept approval	PO	Revisions to be submitted to the PO, 14 calendar days following the receipt of comments
4.	Trial-related Documents	5.b.4	30 calendar days following protocol approval	PO	As required
5.	Final Clinical Trial Report	8.g	90 calendar days following receipt of final study analysis data	PO	As required
6.	Trial Safety Reports	7.a.5	As specified by protocol and safety oversight committee	PO, CTM contractor	As required
7.	Clinical Site Monitoring Plan Template	7.c.1.a	30 calendar days of effective date of contract	PO	Revisions to be submitted to the PO, 14 calendar days following the receipt of comments
8.	Clinical Site Monitoring Plan	7.c.1.b	14 calendar days following protocol approval	PO	Revisions to be submitted to the PO, 7 calendar days following the receipt of comments

9.	Clinical Site Monitoring Reports	7.c.1.c	14 calendar days following monitoring visits	PO	As required
10.	Data management/ quality control Reports	8.a-i	Upon request of PO	PO	As required
11.	Annual clinical trial data reports	8.g	Annual	PO	On/before each anniversary date of the trial
12.	System Security Plan	8.1.h.3	Annual	PO	On/before each anniversary date of the contract
13.	Quality Assessment/ Quality Control (QA/QC) Plan	10	90 calendar days of effective date of contract	PO	Final plan to be submitted to the PO, 14 calendar days following the receipt of comments

C. Copies of reports shall be sent to the following addresses:

Project Officer
Office of Clinical Research Affairs (OCRA)
Division of Microbiology and Infectious Diseases (DMID)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
6610 Rockledge Drive, MSC 6603
Bethesda, MD 20892-6603

Contracting Officer
Office of Acquisitions (OA)
Division of Extramural Activities (DEA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

OPERA
Office of Extramural Inventions and Technology Resources Branch
OPERA, NIH
6705 Rockledge Drive, Room 1040 A, MSC 7980
Bethesda, Maryland 20892-7980

Phase 1 Clinical Trial Unit for Therapeutics Against Infectious Diseases
RFP NIH-NIAID-DMID-08-06

ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS

It is strongly recommended that offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

The following additional Technical Proposal instructions reflect the requirements of the RFP and are meant to provide additional instructions as well as a uniform format for Technical Proposals. The information requested in these instructions should be used as a guide for formatting and preparing the proposal. Offerors should follow the instructions in Section L of the solicitation and include the information requested in this appendix.

Offerors are advised to give careful consideration to the Statement of Work, all reference material, appendices and attachments, the Technical Evaluation Criteria, and the RFP as a whole in the development of their Technical Proposal.

Offerors who propose subcontracts to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration between the prime and subcontractor(s), and the expected advantages of such an approach.

Offerors are reminded that the total page limitation for the entire technical proposal package is 200 pages inclusive of all attachments and appendices.

Pages in excess of the limit will be removed and will not be read, evaluated, or considered in the technical review.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1

A. PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or copy.
B. PROJECT OBJECTIVES, NIH FORM 1688
C. TABLE OF CONTENTS
D. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested limit of 3 pages)

Provide a brief description of the proposed Phase 1 Clinical Trial Unit, including:

A. A description of the activities to be performed by the offeror and those that shall be provided by all proposed subcontractors. This description should include the identification of the proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with degrees and titles. This section should also identify the populations that the offeror and all proposed subcontractors will provide access to for the conduct of Phase 1 safety and pharmacokinetic/pharmacodynamic clinical trials.

B. A brief description of the facilities, equipment and other resources to be made available by the offeror and all proposed subcontractors, including: outpatient and inpatient clinical research facilities, clinical laboratory, research laboratory and research pharmacy facilities, and general clinical research facilities.

SECTION 3: TECHNICAL PLAN/APPROACH

A. Clinical Research Facilities and Resources (SOW Item 1)

1. Provide a description, floor-plans, and documentation of the availability and adequacy of facilities, equipment and other resources available for performance of the contract by the offeror and all proposed subcontractors, including:

    a. Outpatient clinical research facilities
    b. Inpatient clinical research facilities
    c. Clinical laboratory facilities
    d. Clinical research laboratory facilities
    e. Research pharmacy facilities
    f. General clinical research facilities

2. Describe plans for accessing the facilities, services and other resources of affiliated clinical sites when necessary and appropriate to meet contract requirements.

3. Describe plans for and procedures to be utilized to ensure compliance with all safety guidelines and regulations, including training and monitoring of personnel.

4. Describe plans for any change in facilities as necessary due to progress or performance issues that arise during the course of conducting clinical trials.

5. Describe plans for obtaining adequate study-related injury indemnifications for subjects.

6. Provide standard operating procedures for

    a. determining minimal staffing requirements and credentialing of staff for inpatient units
    b. managing emergences in inpatient units
    c. developing, review, and approval of new protocols
    d. handling, shipping, storage and dispensing of investigational products
    e. quality management

B. Scientific and Technical Personnel (SOW Item 2)

The Technical Proposal should include all information relevant to document individual training, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Proposals should include a Staffing Plan for the conduct of the Statement of Work with role descriptions and level of effort of key scientific and technical personnel, including scientific and technical personnel of all proposed subcontractors. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the RFP.

1. *Principal Investigator*: Describe the experience, training, expertise, qualifications, licensure, registration (to administer controlled substances), and percentage of effort of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract. This includes scientific and technical expertise in: the design, conduct and oversight of clinical trials to determine the safety, pharmacokinetics

and pharmacodynamics of investigational therapies. List, in particular, experience in the following areas: the design and conduct of Phase 1 clinical trials of experimental therapies for infectious diseases; monitoring progress, assessing performance, identifying performance problems and implementing corrective actions; collaborating with industry and organizations providing clinical research support services; and leading and directing projects of similar size and complexity.

2. *Pharmacologist and Pharmaco-toxicologist*: Describe the experience, training, expertise, qualifications, and percentage of effort of the proposed pharmacologist and pharmaco-toxicologist. This includes scientific and technical expertise and experience in: interpreting pre-clinical information; the design of Phase 1clinical trials to evaluate investigational therapies for safety, pharmacokinetics and pharmacodynamic. List, in particular, experience in Phase 1 clinical trials of investigational therapies for infectious diseases, and experience collaborating with industry.

3. *Other Key Scientific and Technical Personnel*: Describe the experience, training, expertise, qualifications, and level of effort for all proposed key scientific and technical personnel, including subcontractors. Include experience in designing and conducting Phase 1 clinical trials to evaluate the safety, pharmacokinetics and pharmacodynamic of investigational therapies, particularly for infectious diseases, and in carrying out projects of similar size and complexity. In particular, address experience and expertise in dealing with issues of data management, pharmacy and clinical monitoring.

C. Trial Population and Enrollment Requirements (SOW Item 4)

Provide a plan for the recruitment and retention of the number and type of subjects required to serve as subjects and for enrollment of appropriate subjects. Identify anticipated problems and difficulties that may arise in recruiting and retaining these subjects and discuss proposed approaches to overcome or minimize such problems and difficulties. If subcontracts to affiliated clinical sites are proposed to meet contract requirements, provide a decision-tree for determining when affiliated clinical sites will be required and the criteria to be used to select affiliated clinical sites for specific clinical trials.

D. Protocol Development (SOW Item 5)

1. *Case Study: Phase 1 Clinical Trial of Novel Antibio*tic*:* Provide a scientific, technical and operational plan for the following clinical trial case study. This case study is hypothetical and does not need to represent a real drug. The study will not be implemented upon award and costs to conduct the study should not be included in the overall budget for this solicitation.

Case studies are suggested to be no more than 20 single-spaced pages.

Design a Phase 1 clinical trial to evaluate the safety, tolerability and pK/pD profile of a novel, first in class, new antibiotic. Findings gathered from studies in animal models indicate the following: the antibiotic will have to be taken three times a day, with food; pK studies showed a t1/2 of 5-7 hours and low oral bioavailability due to extensive metabolism by CYP3A4, although AUC was increased by 30-40% with food.

Evidence of dose-dependent and reversible myelosuppression was seen in rats and dogs including decreases in RBC, WBC and platelets. Evidence of mild kidney toxicity (<2-fold increase in BUN and creatinine) was observed only in dogs, in addition to slight, transient elevations in ALT. Decreases in sodium and increases in potassium were also observed.

Discuss the pre-clinical information needed prior to initiation of this clinical trial. If missing information is needed in order to address the following, provide your working assumption on this information including justification and rationale. Provide the following information related to protocol development:

a. Study design and justification
b. Sample size and justification
c. Dosage and route of administration for trial investigational product
d. Sample informed consent forms
e. Description of target population
f. Safety Oversight Structure
g. Inclusion/exclusion criteria
h. Schedule of events and timeline
i. Safety assessments (elements and time points) and complete safety plan (including solicited adverse events and how the Safety Oversight Structure will review such information)
j. Data analysis plan
k. Plan for the recruitment and retention of subjects and a discussion of the feasibility of recruiting an ethnically diverse population in the appropriate age range, with the appropriate health status and in a timely fashion
l. Plans for IRB approval, including historical timelines and any local IRB factors that need to be taken into consideration
m. Feasibility of conducting the clinical trial, addressing adequacy of staffing, facilities, equipment and other resources/services
n. Feasibility of using remote data entry system with data entry turn around time of 72 hours
o. Plans for providing oversight by an Independent Safety Monitor (ISM) and a designated back-up monitor, as well communication plans for adverse events with the proposed Safety Oversight Structure, DMID and industry collaborators
p. Plans for pharmacy support, cold chain maintaining, mixing and supply to the clinic, and clinical specimen storage
q. Plans for laboratory support for screening labs and tests
r. Plans for shipment of sera to a central laboratory
s. Plans for QA/QC of the conduct of the study to ensure compliance with Federal regulations and protocol-specific requirements
t. Plans for specific processes and actions to be implemented to insure that all obligations described in FDA form 1572 are met (see: http://www.fda.gov/cder/forms/1571-1572-help.html)
u. Plans for monitors to have access to data, physical space and availability of study personnel
v. Approaches to the evaluation of safety data based on results obtained
w. Table of contents of the Final Study Report
x. Case Study Technical Cost Summary: a breakdown of direct costs for proposed study-specific personnel by function, position title, and level of effort, and proposed direct costs for supplies, clinical and research laboratory services, research pharmacy services, subject expenses, subject incentives, data collection, management, quality control, advertising and miscellaneous costs, for the offeror and any proposed subcontractors.

2. *Trial-related Materials*: Discuss past experience with and describe proposed plans and procedures to develop, maintain and update trial-related materials. Include the following:

a. The plans and procedures for generating electronic and paper CRFs. Provide examples of CRFs produced for Phase 1 pK/pD clinical trials.
b. The table of contents for a Manual of Operations for a Phase 1 clinical trial.
c. The Data Management section for a Manual of Operations for a Phase 1 clinical trial.

d. The section on handling of trial investigational products for a Manual of Operations for a Phase 1 Clinical Trial Unit.
e. Sections of previously generated protocols that discuss selection of investigational product dose, criteria for inclusion and exclusion of subjects, study procedures and oversight of subject safety. Also provide examples of source documents, questionnaires, memory aids, subject instructions, screening and recruitment logs, order forms for clinical supplies and test articles, and test article accountability logs for Phase 1 pK/pD clinical trials.
f. The plans and procedures for reviewing, updating and distributing trial-related materials to DMID, clinical sites, industry collaborators and regulatory bodies.

E. Protocol Implementation (SOW Item 6)

1. *Institutional Review Boards (IRBs)*: Identify the IRB responsible for the offeror's clinical site and any proposed affiliated clinical sites, and include historical timelines and any local IRB factors to consider in carry out the requirements of the contract. Provide information regarding frequency of meetings and turn-around times for reviewing and approving clinical protocols .

2. *Data Management and Quality Control*: Describe proposed plans and procedures to establish, maintain and update the data collection system and to provide for the quality control of all clinical and laboratory data, including:

a. The number and scope of data collection systems to be developed and the rationale for each. Describe in detail the interaction among and between data systems.
b. The data entry system to be used. Include the minimal requirement for data entry terminals.
c. The plans and procedures for data integrity and quality checks. Include timing, scope, user verification, notifications and security considerations, as well as documentation and established procedures.
d. The plans and procedures for data edits. Discuss compliance with regulatory requirements.
e. The plans and procedures for handling halting rules triggers. Include timing, scope, user verification, notifications and security considerations.
f. The data storage plans. Include a description of back-up procedures, disaster recovery procedures and query abilities.
g. The plans and procedures of the reporting system. Include timing, adaptability and distribution of reports.
h. The plans for freezing and locking databases. Include timing, reversibility and quality assurance plans.
i. The plans and procedures to ensure compliance with regulatory and international guidance requirements.
j. The plans and procedures for computer-based randomization.
k. The plans and procedures to provide security against anticipated risks. Provide the AIS, SSP and COOP.
l. The plans and procedures to provide the database to regulatory agencies and industry collaborators.
m. A description of similar data systems designed, maintained and updated in support of clinical trials.

F. Protocol Oversight (SOW Item 7)

1. Describe experience with NIH safety oversight mechanisms, procedures, capabilities and plans for complying with DMID safety oversight mechanisms, in particular the designation and use of an ISM and back-ups ISM as needed, and reporting capacity for Safety Oversight Structures.

2. Describe experience in developing clinical site monitoring plans, conducting clinical site monitoring, and developing corrective actions to address performance problems and deficiencies identified through the clinical site monitoring process. Provide a plan for the establishment and operation of an independent Clinical Site Monitoring Team, plans for communication with DMID, and the day-to-day operation of the Clinical Site Monitoring Team.

G. Storage, Shipping and Tracking of Clinical Specimens

1. Describe procedures and capabilities for the labeling, tracking and appropriate storage of clinical specimens, and for monitoring of storage conditions.

2. Provide a plan to meet the requirements of the International Transport Association for the shipping of dangerous goods.

3. Provide one sample Standard Operating Procedure for an inventory control system to track, store and ship clinical specimens to be used for microbiological evaluation.

H. Quality Assurance/Quality Control (SOW Item 10)

1. Provide a Quality Assurance/Quality Control (QA/QC) Plan for the management and oversight of the research processes, including plans to standardize contract research processes to ensure that the conduct of any clinical trial and all data generated meet all regulatory standards and other standards (see http://www.niaid.nih.gov/dmid/clinresearch/OP_QM001Rev0.pdf for guidance).
This plan shall include SOPs for establishing and maintaining the QA/QC process. It shall also include a description of the process for internal quality audits of site protocols and a description of remediation procedures for addressing issues when identified.

2. Describe your capability to arrange and accommodate independent auditors and relevant experience in participating in independent audits.

I. Project Management (SOW Item 11)

1. Describe how the project will be staffed, organized and managed. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, and provide an administrative framework indicating clear lines of authority and responsibility for the personnel. Include a diagram of the proposed organizational/management structure for the project.

2. Describe project management systems that will be used to track activities and to keep multiple activities on time and within budget. The plan should include a description of quality control methods that will be used to ensure the effective initiation, implementation, management and oversight of contract activities.

3. Outline how the Principal Investigator will communicate and interact with the Contracting Officer and the Project Officer and how the Principal Investigator will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

4. Provide a plan for how the Contractor and any proposed subcontractors will safeguard confidentiality and intellectual property of data and materials provided to them by third parties or the United States Government, as well as data generated during the contract.

5. Describe plans for collaborating with the CTM contractor to facilitate study implementation, assess study progress and evaluate processes and procedures with respect to the following activities: site assessments,

comparison and reconciliation of the clinical Adverse Event (AE) database with the pharmacovigilence (PVG) Serious Adverse Event (SAE) database; reporting on halting rules; Safety Oversight Structure reporting; and study site-specific reporting.

6. Discuss the access that DMID will have to the clinical database, addressing such issues as format of data presented, tools available to allow efficient monitoring of clinical trials and plans to maintain the integrity of the data base.

7. Describe plans for collaborating with the DMID Clinical and Regulatory Affairs Support contractor with respect to specimen tracking and inventory.

J. Additional Documentation Required Under Section L of the Solicitation

1. **Human Subjects**

   Section L of the RFP specifies the minimum documentation requirements for Human Subject compliance. All related documentation should be included in the proposal in a clearly marked section. The Technical Proposal should document all information necessary to evaluate Human Subjects assurance.

2. **Sharing Research Data (Plan)**

   Section L of the RFP specifies the minimum documentation requirements for Data Sharing. All related documentation should be included in the proposal in this clearly marked section. The Technical Proposal should include a plan for Data Sharing as required by this RFP.

3. **Biohazard Safety**

   The Technical Proposal should include a plan for biohazard safety and security requirements.

4. **Information Technology (IT) Systems Security**

   Section L of the RFP specifies the minimum documentation requirements for IT Systems security. All related documentation should be included in the Technical Proposal in this clearly marked section. The Technical Proposal should include a plan for IT Systems security as required by this RFP.

5. **Any other documentation in support of your Technical Proposal.**

Phase 1 Clinical Trial Unit for Therapeutics Against Infectious Diseases
RFP NIH-NIAID-DMID-08-06

ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS
and UNIFORM BUDGET ASSUMPTIONS

In addition to the format requirements for the business proposal that are contained in Section L of the solicitation, the information provided in this appendix is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as appendices and attachments, and the Technical Evaluation Criteria, and, the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your Business Proposal. Offerors should consider and include the information requested in this appendix, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL

SECTION 1 – PROPOSAL COVERSHEET –
Form NIH-2043 - PROPOSAL SUMMARY AND DATA RECORD

SECTION 2 – COST OR PRICE SUPPORT

The following uniform cost assumptions shall be used by all offerors in preparation of their cost proposal.

1. **Clinical Trials and Subjects** – Offerors should assume the following:

   a. 4 protocols will be initiated in each year of the contract period of performance.
   b. All 4 protocols will be Phase 1 safety and pK/pD trials of investigational therapies.
   c. 2 of the trials to be conducted each year will test new-class compounds, and 2 of the trials to be conducted each year will test established-class compounds.
   d. The Contractor shall be responsible for developing the protocol and other trial-related documents (as outlined in SOW item 5.b.) for all trials.
   e. The duration for each trial, from Concept Proposal through closure, will be 1 year.
   f. The Contractor will provide the data management for all trials.
   g. Recruitment of 150 healthy subjects (18 - 45 years of age) each year including at least 45% of study subjects from minority groups. The gender distribution will be 1:1.
   h. Each trial will include a 7-day inpatient portion with telemetry observation of all subjects.
   i. Each trial will include an additional 14-day outpatient portion. The outpatient portion will include 4 visits.
   j. 2 of the trials to be conducted each year will be carried out with dose escalation and will require 2 safety reports for the Safety Monitoring Committees.
   k. For each trial, there will be 3 clinical site monitoring visits per year, each of 1-2 days in duration.

2. **Investigational Products**

   Investigational products to be evaluated in Phase 1 clinical trials will be provided at no cost to the Contractor.

3. **Clinical Specimens**

Assume that the following number of specimens will be collected for each subject in each trial for the contract period of performance:

a. 60 blood specimens for pK trials. Assume all will be shipped off-site for analysis.
b. 20 blood specimens for screening and safety laboratory tests. Assume analysis will be conducted on-site.
c. 10 blood specimens for special laboratory tests (e.g., troponins). Assume analysis will be conducted on-site.
d. 60 urine specimens for pK trials. Assume all will be shipped off-site for analysis.
e. 10 urine specimens for screening and safety laboratory tests. Assume analysis will be conducted on-site.

4. **Subject Costs**

Assume a total of $150,000 per year (with an appropriate escalation rate in years 2-7) to defray the costs incurred by subjects during participation in clinical trials.

5. **Meetings and Teleconferences**

a. *Contract Initiation Meeting*: Assume one meeting in the Bethesda, Maryland area within 60 calendar days of the effective date of the contract to discuss contract initiation. Assume that this meeting will require a two-night stay and shall be attended by all of the Contractor's key personnel

b. *Site Initiation Meetings:* Assume one, 1-day meeting for each Contractor- and subcontractor-operated site to be held within 180 calendar days of the effective date of the contract. The purpose of these site initiation meetings is for Contractor and subcontractor personnel and DMID staff to establish lines of communication and to review NIAID guidelines and operating procedures. Assume that the Contractor and each subcontractor will host these 1-day meetings at their respective sites. Offerors shall assume that 5 Government personnel and all personnel from the clinical site will attend. Travel and per diem costs for the Government personnel shall not be provided by the contract.

c. *Annual Meetings*: Assume 1 meeting per year in the Bethesda, Maryland area to discuss clinical trial status, progress and issues. Assume that the annual meeting will require a two-night stay and shall be attended by all of the Contractor's and subcontractors' key personnel.

d. *Protocol Specific Meetings and Teleconferences*: Assume 4 protocol-specific meetings per year and 50 protocol-specific teleconferences per year. Assume that meetings will require a two-night stay in the Bethesda, Maryland area and shall be attended by all of the Contractor's key persnnel, including personnel from affiliated clinical sites.

e. *Annual Site Visits*: Assume that the Contractor shall host an annual 2-day site visit at the Contractor's facilities. Offerors shall assume that 5 Government personnel and 2 key personnel from each affiliated clinical site will attend. Travel and per diem costs for the Government personnel shall not be provided by the contract. Offerors shall assume that each Annual Site Visit Report will be 10 pages in length.

f. *General Scientific Meetings*:

1) Offerors shall propose a total of $10,000 annually for the Principal Investigator and selected clinical investigators for travel to general scientific meetings for presentations of work conducted under this contract.

2) Offerors shall propose $5,000 annually for nursing staff travel to scientific meetings for presentations of work conducted under this contract or for updating of clinical research knowledge/skills.

g. *FDA Meetings and Teleconferences*: Assume that the Principal Investigator shall be required to participate in 6 teleconferences and 1 meeting per year with the FDA to be held in the Bethesda, Maryland area.

6. **Independent Audits**

Assume costs for 4 independent audits per year to ensure that the Contractor and/or subcontractor facilities and all planned procedures meet FDA regulations and guidance for GCP standards.

DMID-FUNDED CLINICAL RESEARCH SUPPORT SERVICES CONTRACTS

Phase 1 Clinical Trial Unit for Therapeutics Against Infectious Diseases
RFP NIH-NIAID-DMID-08-06

DMID Clinical Trials Management Support Contract

PPD Development, LP, located in Wilmington, NC, provides clinical trials management support to DMID and DMID investigators. PPD Development specific responsibilities include, but are not limited to, the following:

1. Clinical site assessment, evaluation of clinical site for clinical research feasibility and capacity;
2. Clinical site preparation and clinical trial operations assistance; study document preparation and review;
3. Establish and assist clinical sites with internal quality control and quality assurance;
4. Provide Good Clinical Practices training;
5. External clinical site monitoring to include site initiation, interim and close-out visits and quality audit visits;
6. Centralized pharmacovigilance and safety monitoring; and
7. Information and document management through web-based systems.

DMID Clinical and Regulatory Affairs Support Contract

Fisher BioServices Corporation, located in Rockville, MD, provides regulatory support services, including:

1. Preparation and maintenance of Investigational New Drug (IND) applications;
2. Consulting and audit for manufacturers of NIAID/DMID investigational products; Management and operation of a clinical agent repository for distribution and tracking of IND products.

ADVANCE UNDERSTANDINGS

Phase 1 Clinical Trial Unit for Therapeutics Against Infectious Diseases
RFP NIH-NIAID-DMID-08-06

1. All data and other information pertaining to therapeutic candidates supplied by companies serving as industry collaborators for the clinical trials to be undertaken by the Contractor, or supplied by the Project Officer, shall be assumed to be confidential unless specifically identified as not confidential in writing by the Project Officer. The Contractor agrees that its Principal Investigator and/or any other employees or agents of the Contractor will provide the data generated under this contract exclusively to the NIAID or, if directed by the NIAID, to the Companies and the U.S. Food and Drug Administration (FDA) or other appropriate Federal agency.

2. The Contractor understands that the NIAID must negotiate individual agreements (e.g., Clinical Trial Agreements) with various Companies to obtain therapeutic candidates and that the terms of the agreements may vary. The NIAID intends that these agreements will provide for the Contractor's right to publish results generated by the Contractor under this contract after a reasonable period of time to allow the Companies to file patent applications and to protect their proprietary information. The Contractor agrees to abide by the terms of these agreements that the NIAID has executed unless in direct conflict with the terms of this contract.

3. The Contractor agrees to enter into confidentiality agreements with the Companies when required by the Companies. The confidentiality agreements shall reference this contract by contract number and shall be consistent with any agreement the NIAID has entered into with the Companies to obtain therapeutic candidates. In the event the Contractor reasonably objects to the terms of the confidentiality agreement, the Contractor shall promptly bring such objection in writing to the attention of the Contracting Officer for appropriate resolution.